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Cultivating awareness by living mindfully: CALM

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Doctoral Project

CULTIVATING AWARENESS BY LIVING MINDFULLY: CALM

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Wherever you go, there you are.

Jon Kabat-Zinn

DEDICATION

I want to dedicate this work to my beautiful family for their ongoing support and encouragement throughout this doctoral project and to my husband, Yotam, who constantly inspires me to follow my dreams.

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I want to thank my academic mentor, Dr. Liat Gafni-Lachter, who has been much more than an inspiring academic mentor, but also my biggest believer, my emotional support, and most of all, my friend.

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CULTIVATING AWARENESS BY LIVING MINDFULLY:

CALM

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ABSTRACT

Traumatic brain injury (TBI) contributes to global mortality and disability more than any other traumatic injury. Individuals who sustained a TBI undergo profound changes in their cognitive, physical, and emotional functions. Noticeable behavioral changes include irritability, aggression, low self-awareness, impulsivity, rumination, and more. These contribute to the individual's inability to control emotions and thus participate in interactions and activities, naturally influencing the person, their environment, and the community.

While traditional therapy approaches are beneficial for some of the mentioned challenges, extensive evidence shows that emotional regulation is not effectively addressed, often resulting in behavioral outcomes in the therapeutic environment alone. Mindfulness interventions focus on the present moment's thoughts, sensations, and surroundings with an open and curious mindset, helping participants cope with stressors that often lead to anxiety and problematic behavioral patterns. Nevertheless, the standard Mindfulness does not accommodate the TBI-related challenges.

Cultivating Awareness by Living Mindfully (CALM), is a Mindfulness-based group intervention for adults who sustained a TBI. It aims to increase self-awareness and

improve emotional regulation by practicing mindfulness techniques and implementing them in everyday activities and interactions. This 12-week program is low-cost and easily applicable to a variety of practice and community settings. The program incorporates principles from the latest evidence-based therapy approaches and is designed specifically to accommodate TBI-related challenges. The theoretical foundations consist of complementing knowledge bases including Mindfulness, the occupational therapy framework - the multi-context approach, and brain-based learning, which are principles from the latest research on optimizing learning for this population. This combination of frameworks aims to makes Mindfulness and its many associated health benefits accessible for individuals post-TBI. This doctoral paper includes a plan for program evaluation, funding, and dissemination.

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ACT	Acceptance Commitment Therapy
BU	Boston University
CBT	Cognitive Behavioral Therapy
CFT	Compassion-Focused Therapy
CR	Cognitive Rehabilitation
MC	Multi-Context
OT	Occupational Therapy
TBI	Traumatic Brain Injury

CHAPTER ONE – Introduction

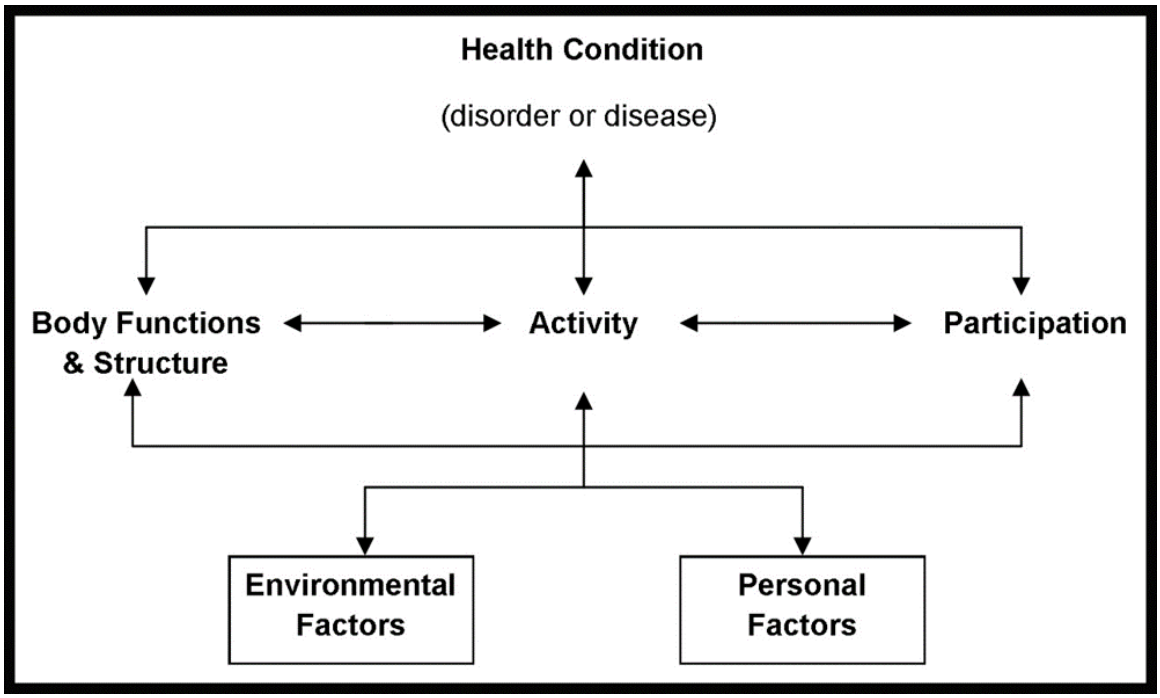
Background

Traumatic Brain Injury (TBI), also known as the "silent epidemic," contributes to global mortality and disability more than any other traumatic injury (Dewan et al., 2018). This introduction chapter present the background for the development of a unique intervention program focused on improving emotional regulation of people who sustained a TBI. A TBI is a disruption to normal function of the brain, caused by a bump, blow, or jolt to the head (DCD, 2019). Approximately 5.3 million Americans live with TBI-related disabilities in the United States (Selassie et al., 2008; Zaloshnja et al., 2008). A large systematic review (Dewan et al., 2018) estimated that every year approximately Sixty-nine million individuals sustain a TBI around the world annually. The latest and most comprehensive study, conducted in 2010, suggested that the total cost related to TBIs in the United States alone is $76.5 billion, including medical expenses, loss of productivity, and more (CDC, 2019; Humphreys et al., 2013). Beyond the substantial financial impact of TBIs on the global economy, the emotional and social effects invoked by TBIs weigh a significant burden on society.

The International Classification of Functioning, Disability and Health (ICF) is used to describe the extent of the problem (see chapter 2). The ICF addresses several factors that influence rehabilitation including Body structures and functions, Ability to perform activities and participate in society, Environmental barriers and facilitators, and Personal factors (WHO, 2001). Figure 1.1 presents the ICF model.

Figure 1.1

ICF Model (WHO, 2001)



Body Function Outcomes

People who undergo a TBI experience changes in cognitive function, physical function, and emotional function. Major behavioral changes reported following a TBI consist of personality changes, severe difficulties in temper control, irritability, physical aggression, low self-awareness, impulsivity, social disinhibition, rumination, depression, and anxiety (King et al., 2013; Seel et al., 2003). Furthermore, people who sustain a TBI often deal with depressive symptoms that include diminished interest or pleasure, and being easily angered or irritated, contributing to the client's isolation from society (Seel et al., 2003). These changes in emotional regulation led to difficulties in paying attention to

the mind and the present moment, resulting in automatic, uncontrolled behavior (Mateer & Sira, 2006; Seel et al., 2003).

Environmental Outcomes

The range of challenges related to a TBI extend to the individual's environment. Following the injury, family members cope with “losing” the person they knew and learning to accept the changed personality of their loved one. Coping with extreme behaviors can negatively impact families and caregivers' quality of life (Kolakowsky-Hayner, Miner, & Kreutzer, 2001). The effects of a TBI contribute to the individual's inability to control emotions and thus maintain and form social relationships and participate in life events and activities (Manolov et al., 2019; Mateer & Sira, 2006; Toglia & Golisz, 2017). Cognitive and emotional changes coupled with TBI related physical limitations, frequently result in conflicts with the social environment, and struggles to reintegrate into the community (Fleming et al., 2014; Mahar & Fraser, 2011).

Participation and Activity

TBI is associated with restricted participation in activities (Erler et al., 2018; Goverover et al., 2017; Kersey et al., 2020). The individuals who sustained a TBI often find it challenging to take part in social activities and participate in meaningful occupations and interactions (Wise et al., 2010). These difficulties contribute to the person's isolation, reduce their confidence, and promote a less mindful state. Moreover, environments are also restrictive and not always accessible to people with physical or cognitive impairments (Sveen et al., 2013).

Personal Factors

Individuals with TBI report lower self-esteem in personal, academic, social, and family domains, and an unstable self-definition. They perceive themselves as having poor performance, and difficulties taking new tasks, responsibilities, or social risks (Ponsford, Kelly, and Couchman (2014). Individuals with TBI find it hard to come to terms with their disability. Acceptance of the disabilities relates to a positive, less depressed, and less somatically concerned state of mind, whereas un-acceptance of the disability relates to challenges in emotional regulation and behavioral problems including anger outbursts, aggression and anxiety (Hoofien et al., 2001).

Personal Experience

At the rehabilitation center for Israeli veterans in Tel Aviv, the impact of these emotional difficulties on the functioning and participation of the members is noticeable. The comprehensive rehabilitation program provided is holistic and beneficial. Nevertheless, it does not address these challenges of emotional regulation effectively. Tom, a 27-year-old veteran, was injured during his military service. Tom came to the center two years after his injury, coping with cognitive and emotional challenges. A significant challenge presented and reported by his family is anger outbursts. Tom often lost control over his behavior and became very aggressive. After a fit, he would be consumed with remorse and guilt, leading him to refrain from social interactions. To address this challenge, we started to integrate mindfulness practice into our occupational therapy sessions. Over time, the outbursts gradually decreased.

Tom stated he learned to "feel" the urge to burst and control it. Like Tom, other clients reported the beneficial impact of the practice. Nonetheless, despite these positive changes and reports, some participants struggled to practice at home and transfer the techniques to other settings outside of the therapy room. This experience led me to apply for this doctoral program, aiming to explore and develop a Mindfulness intervention specifically designed for people who sustained a TBI.

Current Approaches for Intervention

The optimal rehabilitation process for individuals who sustained a TBI is holistic and addresses the various aspects of life. The process requires the services of health professionals from different disciplines, making the rehabilitation process more costly, and often has a limited impact on desired outcomes (Lee, 2019; Sveen et al., 2020). Current traditional approaches and methods for the rehabilitation of people with TBI include pharmacological treatment, cognitive rehabilitation, psychotherapy, behavioral interventions, Cognitive Behavioral Therapy (CBT) and more. While these therapy approaches have been beneficial for some of the mentioned challenges, extensive evidence shows that emotional regulation is not effectively addressed (Cicerone et al., 2011; Gómez-de-Regil et al., 2019; Lee, 2019; Oddo et al., 2016).

In contrast to the current traditional therapy addressing emotional regulation of individuals with TBI, a Mindfulness-based approach focuses on observing and accepting thoughts, sensations, feelings, and surroundings with an open and curious mindset (Alsubaie et al., 2017; Azulay & Mott, 2016). Mindfulness interventions are becoming

increasingly prevalent, with growing evidence of their benefits for the brain injury population (Marchand et al., 2021; Moulton-Perkins et al., 2020). Nevertheless, the standard Mindfulness interventions available for adults with TBI do not accommodate for the specific challenges these individuals cope with (Combs et al., 2018; Kristofersson et al., 2016; Ylvisaker et al., 2001), making it inaccessible and less effective. Therefore, there is a need for a Mindfulness-based intervention program that is specifically developed for this population, based on principles of cognitive rehabilitation, and learning approaches.

Occupational Therapy Practice Concerns

The Occupational therapy profession acknowledges the significance of the mind–body–spirit connection on the individual's participation daily activities and interactions (OTPF, 2020). The effects of TBI on a person's life are vast. All of the symptoms discussed above greatly influence a person's ability to participate in all aspects of life. Including difficulties performing I/ADL, sustaining a job, interacting in social situations, managing finance, raising children, and more. "Occupation is used to mean all things people want, need, or have to do…whether occupations are contemplative, reflective, meditative or action based" (Durocher, Rappolt, & Gibson, 2014). Developing an intervention that focuses on emotional regulation and the state of mind directly relates to our mission as OTs, as a person's state of mind has an enormous effect on their ability to perform in their perceived and desired life roles. The proposed intervention will enable the participants to improve self-regulation, increase awareness, and Mindfulness traits, providing them more control over their behavior and ultimately, increasing their

participation and performance in all aspects of life.

The Proposed Program

In this doctoral project, I present Cultivating Awareness by Living Mindfully (CALM). This is an innovative program focused on harnessing the benefits of Mindfulness practice to increase self-awareness and emotional regulation of people who sustained a TBI. The theoretical foundations are based on complementing knowledge bases: The content and techniques are based on Buddhism and Mindfulness. The delivery approach and adaptations for cognitive impairments (such as memory and attention) are based on Mindfulness-based interventions for TBI, occupational therapy's the MultiContext approach (Toglia, 1991), and brain-based learning.

The CALM program consists of 12 weekly lessons with 6-8 participants. Each week includes an in-person group session, followed by an online session delivered in the persons' home. The sessions are focused on learning concepts related to Mindfulness and emotional regulation and practicing a variety of Mindfulness techniques in different settings and contexts. The details of the program can be found in chapter 4 of this paper.

Summary and Project Overview

This chapter provided the background and rational for the development of the CALM intervention program. The following chapters include elaborations on all the aspects related to creating and implementing CALM. Chapter two of this doctoral project presents the theoretical framework which informed the explanatory model of the problem and provides a thorough review of the evidence supporting the associations presented in the model. This chapter is focused on the nature and impact of a traumatic brain injury on

the person and their environment.

Chapter three of the doctoral paper will review the current approaches and methods used to address these challenges. Chapter four presents the theoretical frameworks and approaches that are the foundation of the CALM intervention program. Chapter five presents a detailed plan for the evaluation study, aiming to establish the connection between the CALM program and the expected outcomes. Additionally, chapter six outlines the planned actions and activities for the dissemination of the proposed program. Chapter seven presents the funding plan for the CALM program and includes a detailed table describing the expected costs of the intervention. Finally, chapter eight contains a summary of the doctoral paper and conclusions for implementation of the program as well as future considerations.

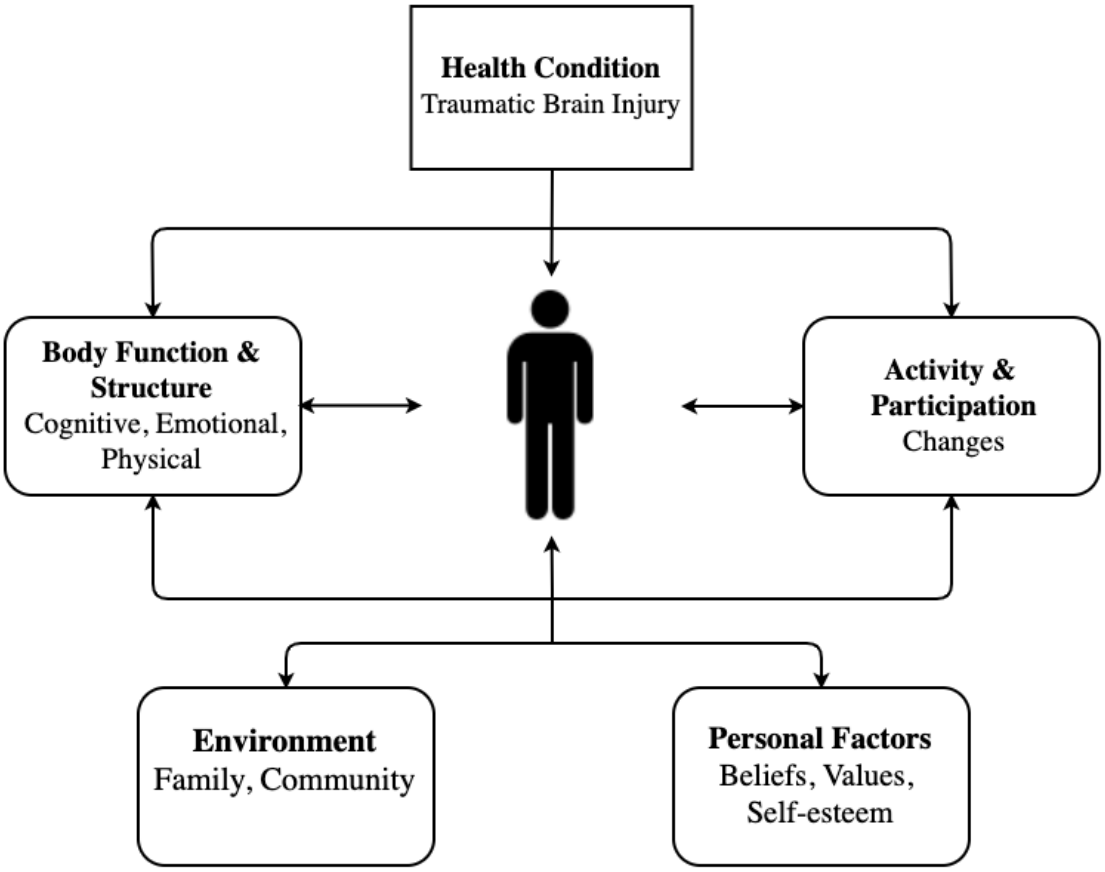
CHAPTER TWO –Theoretical Framework of the Problem

Introduction

This chapter presents the theoretical framework which informed the explanatory model of the problem and provides a thorough review of the evidence supporting the associations presented in the model. The chosen theoretical framework is the International Classification of Function, Disability, and Health. The ICF was formed "to provide a scientific basis for understanding and studying health and health-related states, outcomes and determinants" (Simkiss, 2008, p. 149). It outlines the interrelationships between the health condition, body functions and structures of people (cognitive, emotional and physical functioning); the activities of people, and the activity limitations they experience; the participation or involvement of people in all areas of life, and the participation restrictions they experience, and the personal and environmental contexts. The ICF conceptual framework offers many potential benefits, from enhancing communication to designing rehabilitation programs and promoting health policy design and implementation (WHO, 2001). The ICF views disability as a dynamic state in which the person's function and context are mutually affected by one another (Laxe et al., 2011). Furthermore, the ICF has been widely used for exploring function and rehabilitation of the TBI population (Laxe et al., 2011; Sveen et al., 2013). Therefore, an intervention targeted at one of the domains may well cultivate a change in all ICF domains. The explanatory model of the problem addressed in the doctoral project is hereby presented according to the ICF model in Figure 2.1.

Figure 2.1

Visual Model of the Problem



A Traumatic brain injury (TBI), caused by a bump, blow, or jolt to the head is defined as a disruption to the normal function of the brain (Peterson et al., 2019). TBI, also known as the "silent epidemic", contributes to global mortality and disability more than any other traumatic injury. Nevertheless, the exact prevalence and occurrence of TBI remains unknown. National investigations estimate that approximately 5.3 million people live with TBI-related disabilities in the U.S. (Selassie et al., 2008; Zaloshnja et al., 2008). A large systematic review (Dewan et al., 2018) revealed that approximately Sixty-nine million individuals are estimated to suffer TBI from all causes each year around the

world. The latest and most comprehensive study, conducted in 2010, suggests that the total cost related to TBIs in the United States alone is $76.5 billion, including medical expenses, loss of productivity, and more (Humphreys et al., 2013; *TBI*, 2019). Beyond the substantial financial impact of TBIs on the global economy, the emotional and social effects invoked by TBIs weigh a significant burden on society.

Individuals who sustained a TBI experience changes in multiple factors that interact with each other and result in the functional outcome. These factors include:

- Body Function & Structure - this factor includes impairments in cognitive capacities (decreased memory, attention, problem-solving), emotional regulation (aggression, irritability), and physical changes (visible changes in appearance and physical limitations).
- The social environment - the environment is also both influenced and influencing the person's function. For this project, the social environment Includes the family, the larger community, and the therapeutic care team.
- Activity and participation - difficulties resulting related to the TBI and impaired body structures restrict the person's ability to complete desired tasks, to take part in social activities, or to engage in negative interactions. Lack of positive activity and participation can further exacerbate the condition by limiting access to positive opportunities to enhance all other causal factors.
- Personal Factors - The person's self-esteem, beliefs, and values. An evolving term is the cognitive functional narrative, which describes the individual's perception of his function.

All these changes, caused by TBI, influence the person's state of mind and well-being, his or her close environment, and the community as a whole.

Review of the Evidence

An extensive literature review was conducted to evaluate evidence that supports the relationships presented in the explanatory model. Following consultation with a librarian, PsycINFO, CINHAL, BU library search, and PubMed databases were used, and key terms were matched to each search question. The findings are presented below.

Associations Between TBI and a Person's Body Structure and Function

People who undergo a TBI experience vast changes in body structure and function, including cognitive, physical, and emotional functioning (O'Keeffe et al., 2020; Tam et al., 2015; J. Toglia & Golisz, 2017b). These changes are outlined in the following sections.

Cognitive Function

Evidence consistently demonstrates the vast impact of TBI on cognitive functions, with approximately 65% of patients with moderate to severe TBI reported long-term difficulties with cognitive functioning (Dikmen et al., 2009; Rabinowitz & Levin, 2014; Seel et al., 2003; Winter et al., 2018). Hoofien et al. (2001) examined the long-term impacts of TBI on 76 individuals. The researchers found that the overall intellectual functioning of the participants was within the lower range of the average ability. Furthermore, the study revealed a general slowing in psychomotor ability and processing speed as well as memory impairments and learning deficits. A large systematic review found that people with TBI experience neurological disorders

including attention difficulties, speech and language impairments, difficulties in memory and learning, and impairments in planning, reasoning and problem-solving skills (Kuboy, 2018). A nationwide multicenter study, including 666 patients with TBI from 17 centers who received follow-up assessments, found that diminished thinking ability and problems with concentration and memory were frequently endorsed. 28% of patients reported that they often or always were easily distracted, whereas. About 20% said each of the following as problematic: poor concentration, forgetting whether they had done things, and forgetting yesterday's events (Seel et al., 2003).

Emotional Function

Emotional changes resulting from TBI include a myriad of disruptions to emotional regulation (Van der Horn et al., 2016) such as disinhibition, social inappropriateness, agitation, aggression, or lability, and amplification of premorbid traits (Vaishnavi et al., 2009). Elevated anxiety and depression are common psychiatric symptoms after TBI (Bombardier et al., 2010). Damage to the prefrontal cortex, particularly the orbitofrontal and ventromedial regions commonly seen after Traumatic brain injuries, has been associated with increased hostility, impulsivity, and aggression (Kim, 2002).

A recent large study explored the trajectory of irritability, anger, and aggression behaviors after a TBI. The study found that over 50% of the participants presented irritability, anger, and aggression after a post-acute rehabilitation setting (Miles et al., 2021). A cohort study that examined 559 hospitalized adults with mild to severe TBI found that 53% met the criteria for major depression at least once in follow-up. Those

with Major Depressive Disorder (MDD) were more likely to report comorbid anxiety disorders after TBI than those without MDD. Those with MDD reported lower quality of life (QOL) at one year post injury (Bombardier et al., 2010). Baguley et al. (2006) examined the prevalence of aggressive behavior in 228 patients with moderate to severe TBI. They found that at any given follow-up period, 25% of the participants were classified as aggressive, with depression as the most significantly associated factor with aggressive behavior at all times postinjury. In the nationwide study conducted by Seel at al. (2003), 26% of patients reported feeling "easily angered or irritated." Similarly, 25% of the patients reported feeling frustrated and had difficulties with rumination. Feeling sad was reported by 18% of the sample, and 12% reported feeling hopeless often or all the time. 16% of patients reported arguing as a significant problem, and 8% said they sometimes hit or pushed others. Seven percent reported that they sometimes threatened to hurt themselves, and 2% reported threatening to do so often. Fann et al. (2004) conducted a prospective study with 939 randomly selected participants; They discovered that the prevalence of any psychiatric illness in the first year after a TBI is 49% following moderate to severe brain injury and 34% following mild TBI.

One of the obstacles to the rehabilitation process after brain injury is diminished awareness of difficulties (Fann et al., 2004). After a TBI, the person may not be fully aware of physical impairments, limitations in activities, or changes in thinking skills, emotional control, and behaviors (Toglia & Golisz, 2017). Winter et al. (2018) state that impairments in ER should be regarded as a risk factor for poor interpersonal outcomes, a target for mental health treatment, and a focus for interventions aimed at improving

psychological well-being in TBI.

Physical Function

Physical changes following TBI include a wide range of symptoms such as seizures, spasticity, fatigue, insomnia, visual deficits, balance problems, dizziness, pain, mobility limitations, fine motor deficits, and more (McNamee et al., 2009). Deficits in mobility and upper extremity function are estimated to affect 30% of those who have experienced a TBI (Capó-Lugo et al., 2019). Long-term follow-ups of individuals with TBI show that mobility limitations undergo little change, even 10 years after the initial injury (J. L. Ponsford et al., 2013). Seel et al. (2003) found that fatigue during physical activity was among the most frequently reported physical concerns, with 56% of the sample reporting it as a problem, and 29% reporting being tired often or all the time. Nampiaparampil's (2008) conducted a systematic review of 23 studies on the prevalence of chronic pain after TBI. The review included 4206 patients and revealed that pain complications, which is a common complication of TBI, and includes headaches, complex regional pain syndrome (CRPS), peripheral neuropathic pain, chronic neck/ shoulder, back, and other pain symptoms are independent of psychological disorders such as post-traumatic stress disorder PTSD and depression and is common even among patients with apparently minor injuries to the brain. Their review of 3289 civilian patients with TBI yielded a chronic pain prevalence of 51.5%. Higher pain severity was associated with increased severity of PTSD, depression, reduced satisfaction with life, and avoidant coping style (Nampiaparampil, 2008). Furthermore, physical outcome following TBI is a strong predictor of subjective mental and physical health (Capó-Lugo

et al., 2019).

TBI affects the person in breadth and depth, altering body functions which inevitably alter health and participation in the long term. The next section will review the relationship between a TBI and a person's environment.

Associations Between TBI and the Social Environment

Evidence consistently demonstrates that the effect of a TBI extends to the person's environment (Fleming et al., 2014; Temkin et al., 2009). The cognitive and emotional difficulties resulting from TBI, impact the individual's overall function (Mahar & Fraser, 2011). In particular, the person's ability to endure change and control temper outbursts (Winter et al., 2018). These changes coupled with TBI related physical limitations, frequently result in conflicts with the social environment and struggles to reintegrate into the community (Fleming et al., 2014; Mahar & Fraser, 2011).

TBI and Family

Studies point to significant associations between changes in the person with TBI and their family's functioning and well-being (Ponsford & Schönberger, 2010; Pugh et al., 2018). Following the injury, family members report the notion of losing the person they knew (Blais & Boisvert, 2005). The process of coping with the new reality, disabilities, and the changed personality is stressful and painful for families (Blais & Boisvert, 2005; Mahar & Fraser, 2012).

In a large randomized controlled trial with over 300 participants and their relatives, Ponsford and Schönberger, (2010) examined the impact of brain injury on family functioning and quality of life. Over half (53%) of the participants and their

relatives reported significant symptoms of anxiety two and five years after the injury. Other studies corroborated this finding, showing a strong correlation between a person's behavioral changes and decreased family functioning, feelings of depression, and anxiety in the family (Mahar & Fraser, 2011; Pugh et al., 2018; Sveen et al., 2013; Temkin et al., 2009) as well as diminished social interaction and isolation (Blais & Boisvert, 2005). Blais and Boisvert, (2005) explain that caregiving spouses of individuals with TBI lose their major source of emotional support and partnership and report a loss of sexual intimacy and empathic communication

TBI and Community Reintegration

Community reintegration following a TBI is a significant challenge. Between 26% to 45% of people with brain injury are inadequately integrated back to society (Mahar & Fraser, 2012). Mahar and Fraser (2012) attribute the limited community reintegration to aspects in the person, such as inappropriate and aggressive behaviors, mental and physical fatigue. Other studies emphasized barriers in the community including the physical, attitudinal, service, and policy environments; physical barriers having the greatest influence on overall community integration (Fleming et al., 2014; Sveen et al., 2013).

A study that examined the association between TBI severity and community reintegration outcomes as well as return to work status among 2023 veterans found that chances of employment among individuals with moderate to severe, and unclassified TBI were significantly lower relative to those with no TBI; Furthermore, women reported significantly more difficulty with community reintegration and were significantly less

likely to be employed (Pugh et al., 2018).

TBI in the Therapeutic Environment

Limited information is available on the therapeutic challenges occupational therapy and other health professionals experience with clients who sustained a TBI. However, two articles explored the therapeutic difficulties that arise in the psychotherapy of this population and can provide insight to struggle in other health disciplines. As to be expected, the challenges described above portray themselves in the therapeutic environment as well as impacting the therapeutic relationship and progress (Canto et al., 2014; Judd & Wilson, 2005). Judd and Wilson, (2005) surveyed psychologists who provide therapy for individuals who sustained a brain injury. They found that the most significant challenges in therapy were due to TBI symptoms including memory lapses, inflexible thinking, poor attention, and communication difficulties. Participants also shared that they had experienced negative emotional reactions to their clients and the challenges of establishing a working alliance. Similar findings were reported by Canto et al. (2014) who also illuminated communication problems as the most significant barrier in forming a solid therapeutic relationship.

Associations Between TBI and Participation in Activities

TBI is associated with restricted participation in activities (Erler et al., 2018; Goverover et al., 2017; Kersey et al., 2020). The individuals who sustained a TBI often find it challenging to take part in social activities and participate in meaningful occupations and interactions (Wise et al., 2010). Environments are also restrictive and not always accessible to people with physical or cognitive impairments (Sveen et al., 2013).

A study by Goverover et al., (2017) examined past and current participation levels of 52 people with moderate to severe TBI and 30 healthy controls. They found that activity participation following TBI was significantly lower than that of healthy controls in the majority of measured domains, including household activity, leisure activity, and social activities. Participants with TBI reported reduced participation in all activities from before to after the injury.

Similar findings were found by Wise et al., (2010) who conducted a prospective evaluation of leisure participation at one year after a moderate to severe TBI in 160 rehabilitation patients. They found that 81% had not returned to preinjury levels of leisure participation. Most participants engaged in a reduced number of less social leisure activities one year after injury. The activity most often reported as new after the injury was watching television. Kersey and Skidmore (2020) examined 61 participants who sustained a TBI and live in a community setting. The participants' goals revealed that community participation (work, socialization, recreation, and learning) was identified more frequently than personal care or mobility goals. These results suggest that community participation may remain problematic and essential throughout the rehabilitation process.

Associations Between TBI and the Individual's Personal Factors

The term 'personal factors' has yet to be classified by the ICF (WHO, 2001). There is no international agreement on this domain's components due to the social and cultural diversity associated with them and the ethical concern that they will be misused for the person's 'classification' (Badley, 2006; Ditchman et al., 2016). Nevertheless,

several experimental studies have identified the essential aspects of the personal factor's domain (Heerkens et al., 2017; Perin, 2017). These include sociodemographic factors (e.g., age, gender, ethnicity), position in immediate social and physical context (e.g., housing, income, position in the family, social networks), personal history and biography (e.g., major life events, premorbid personality), and mental factors/psychological assets (e.g., self-esteem, coping capacity, acceptance, self-efficacy).

Mental Factors and Psychological Assets

In a study examining grief and self-identity, adults with TBI experienced significant changes in their self-concept with a negative self-perspective compared to pre-injury self. Furthermore, perceived identity change was positively associated with depression and grief and negatively associated with self-esteem and awareness. (Carroll & Coetzer, 2011). Persons with TBI and depression or anxiety tend to considerably underestimate their abilities and self-report more cognitive and physical impairments than observed through testing; This is different from individuals who exhibit unawareness and tend to overestimate abilities (Seel et al., 2010). For example, Kelley et al. (2014) interviewed 62 adults with moderate to severe TBI and their significant other, five to 16 years after acute inpatient rehabilitation. The participants had underreported neurologic symptoms and over reported their work and home functioning; however, their self-ratings of emotional distress and social functioning were similar to their significant other's report.

Ponsford et al. (2014) found that individuals with TBI report lower self-esteem and self-concept in personal, academic, social, and family domains and an unstable self-

definition. They perceived themselves as having performance difficulties and difficulties accepting new tasks and responsibilities. They rated themselves as socially isolated from peers and avoided taking social risks. They also felt more impulsive and saw themselves as "bad" people relative to others. Individuals with TBI that experience lower self-esteem and a more negative evaluation of their coping resources were more likely to respond to threat appraisals with avoidance (Rakers et al., 2018). A study of 97 participants who sustained a TBI found that perceived self-efficacy was the strongest predictor of global life satisfaction, among other variables such as gender, time since injury, satisfaction with productivity, and satisfaction with leisure and social activities (K. D. Cicerone & Azulay, 2007). Caplan et al. (2016) conducted a systematic review of the evidence for self-identity changes after TBI and discovered negative changes to self-identity. For example, Thomas et al. (2014) conducted a concept analysis methodology through 110 articles and discovered that individuals with TBI feel they have lost their individuality or uniqueness due to the injury. This mental state is associated with the loss of independence and autonomy that individuals with TBI often experience.

Evidence consistently demonstrates that individuals with TBI often report struggles to come to terms with their disability (Hoofien et al., 2001; Ponsford et al., 2014). Acceptance of the disabilities relates to a positive, less depressed, and less somatically concerned state of mind, whereas un-acceptance of the disability relates to psychiatric symptomatology and behavioral disturbances (Hoofien et al., 2001).

Summary

The purpose of this chapter was to present the causal factors involved in diminished health and participation for people with TBI. An explanatory model of the factors which may support or hinder the health and participation of persons with TBI was presented, along with supporting evidence. The explanatory model was designed based on the ICF (WHO, 2001) to represent the dynamic systems in which all factors interact and influence the person's overall health and well-being. Specifically, this model recognizes the multidirectional influence of a medical condition on related body functions and structures, activity and participation, and the environmental and personal context. Evidence presented in this chapter confirms that changes in body functions and structures resulting from TBI include cognitive, emotional, and physical manifestations. These manifestations have a direct impact on the person's participation in meaningful activities. As exhibited throughout this chapter, the discussed changes in body functions and reduced participation negatively influence the person's family and his integration in the community. The many changes induced by TBI and described above interact and influence one another, impacting the personal factors, including the CFN of acceptance of the disability, self-esteem, and well-being.

The following chapter will review current approaches and methods for addressing the problem.

CHAPTER THREE – Overview of Current Approaches and Methods

Introduction

Individuals who sustained a traumatic brain injury (TBI) report profound changes in their cognitive, physical, and emotional function. Common changes after TBI include anger outbursts, irritability, physical aggression, low self-awareness, impulsivity, social disinhibition, rumination, depression, and anxiety. The wide range of short and long-term outcomes influences the person, his or her environment, and the community, as outlined in the previous chapter. The rehabilitation of individuals with TBI demands health professionals from different disciplines, including MDs, nurses, occupational therapists, psychologists, physical therapists and more. The optimal rehabilitation process is holistic and addresses the various aspects of the ICF (Alderman, 2003; Fleming & Ownsworth, 2006; WHO, 2001). This chapter will review the current approaches and methods for the rehabilitation of people with TBI, including pharmacological treatment, cognitive rehabilitation, and psychotherapy. The chapter also examines the development of cognitive-behavioral interventions from the first wave of basic behavioral interventions to the second wave of the classic CBT and finally, the arrival of the third wave focusing on acceptance, compassion, and mindfulness-based approaches. As this project aims to address behavioral and emotional regulation challenges, this review will focus on interventions that target difficulties in these domains.

Pharmacological Treatment

Pharmacological treatments given to individuals with TBI in the post-acute stage aim to improve cognitive and behavioral outcomes by reducing the effects of long-term

neurochemical changes (Wheaton et al., 2011). A meta-analysis investigating 19 treatments and 395 participants with TBI revealed that methylphenidate, a dopaminergic agent, helped to reduce aggressive behavior and improve psychosocial function. Additionally, donepezil, a cholinergic agent, improved memory, and attention abilities (Wheaton et al., 2011). Nevertheless, a recent meta-analysis found no significant benefit of antidepressants drugs over placebo in treating depression after a TBI (Kreitzer et al., 2019). Furthermore, the shortage in experienced neuropsychiatrists, the appeal to administer sedative medication, and the sensitivity of people with brain injury to harmful side-effects present potential areas of concern in pharmacological interventions (C. P. Alderman, 2003; Fleming & Ownsworth, 2006; Oddo et al., 2016). Occupational therapists do not prescribe pharmacological treatment, nevertheless, it is essential to be aware of its use among the TBI population.

Cognitive Rehabilitation

Cognitive Rehabilitation (CR) refers to the therapeutic process of increasing or improving a person's capacity to process and use the information to allow increased functioning in everyday life. It aims to restore cognitive functions and utilize methods to compensate for cognitive limitations (Cicerone et al., 2006). Cognitive rehabilitation consists of various approaches such as re-establishing previously learned behavior patterns or establishing new behaviors through internal or external compensatory mechanisms (Ramanathan et al., 2019). Many review studies demonstrated the beneficial effects of cognitive rehabilitation strategies on specific cognitive aspects such as memory, attention, visuospatial abilities, apraxia, and aphasia in people after brain injury

(Cicerone et al., 2006; Cicerone et al., 2011; Kumar et al., 2017). CR methods, including problem-solving training, role-play, and training in compensatory strategies, have also been found beneficial for improving social cognition, including the theory of mind, awareness, and self – control and behavior of people who sustained a TBI (Alderman et al., 1995; Neumann et al., 2017; Ownsworth et al., 2000). Several CR approaches are described below.

Metacognitive Interventions

Cognitive rehabilitation includes metacognitive interventions that utilize strategies to improve awareness. Methods of metacognitive rehabilitation include self-monitoring, post-task self-reflection, and feedback during various tasks (Doig et al., 2020; Finch et al., 2017). Individuals are taught to engage in overt self-talk and self-regulation by problem-solving through hierarchal tasks (Ramanathan et al., 2019). Intervention strategies for individuals with TBI recommended by Toglia and Kirk (2000) include engaging the person in structured experiences that enable self-monitoring and evaluation. With increasing practice, the individual gains mastery over the task, and his metacognitive knowledge is restructured and strengthened. Activities are accompanied by structured self-questioning and self-evaluation methods or videotaped for self-evaluation (Toglia & Kirk, 2000). A study by Ownsworth and Fleming, (2005) provides partial support for a metacognitive contextual intervention aimed to improve self-monitoring in a person with severe awareness deficits, such as after a TBI. Nevertheless, the context-specific training of metacognitive skills did not generalize across settings or show a significant awareness change.

The Multi-Context (MC) approach (Toglia, 1991) targets transfer and generalization as the therapy program's main goals. These goals are achieved through the practice of metacognitive strategies in different contexts to increase awareness and generalization of those strategies. Tasks and environments are increasingly changed, but the strategy and techniques remain the same. Metacognitive strategies include anticipation of challenges, outcomes, and appropriate strategy, self-prediction of necessary performance, which is then compared to self-evaluations after the task. This approach has been found beneficial for improving metacognitive learning, skills generalization, improvement in self-awareness, and self-monitoring in adults with TBI (Blaker et al., 2020; Doig et al., 2020; T. Ownsworth et al., 2010).

Virtual Reality Interventions

Cognitive rehabilitation techniques can be classified as conventional methods such as pen and paper exercises or computer-assisted neurorehabilitation, using cognitive strategies to improve cognitive function. The use of Virtual Reality (VR) allows therapists to monitor the clients through visual and auditory feedback and more accurate measuring of performance. VR offers numerous activities and exercises that can continuously adapt according to the client's performance. VR environments simulate real-life situations such as grocery shopping, crossing the street, and food preparation (Gamito et al., 2017). Virtual Reality is showing promise in improving cognitive and physical abilities after a TBI. VR has been found useful for enhancing motivation and enjoyment in people with TBI and effective in different aspects of rehabilitation, such as improving walking distance and speed, gait and balance, and upper limb function and cognition,

perception, and functional tasks (Gamito et al., 2017; Imam & Jarus, 2014). Nevertheless, the evidence that the use of VR in the rehabilitation of TBI improves motor and cognitive functionality is currently minimal.

Although cognitive rehabilitation methods have been shown to be beneficial, a recent systematic review that included 790 participants and examined the efficacy of cognitive rehabilitation for adults with TBI on occupation outcomes, including community integration and quality of life, revealed insufficient evidence to conclude that cognitive rehabilitation, compared to no other treatment, led to better return to work, community integration, or quality of life in adults with TBI (Kumar et al., 2017). Furthermore, improvements in changing behaviors specific to the situations in which they had been practiced, is often not maintained in new contexts, and the patients continue to exhibit challenges in emotional and social behavior (Cicerone et al., 2006; Cicerone et al., 2011; Fleming & Ownsworth, 2006; Goverover et al., 2007).

Traditional Psychotherapy

Psychotherapy is an integral component of many rehabilitation programs. Psychotherapy aims to address concerns related to emotional and practical adjustment difficulties and help the person reduce their distress and improve their well-being by changing their thoughts, feelings, and behavior (Block & West, 2013; Hart et al., 2020; Liu et al., 2002; Rochat et al., 2019). The focus of psychotherapy after brain injury is to help the person explore the meaning of their loss and impairments (Block & West, 2013) and re-establish a sense of purpose in their lives (Klonoff, 2010).

Essential aspects of psychotherapy include psychoeducation that should occur at

the beginning of therapy, The therapeutic relationship that develops during therapy, In-session impacts including emotional relief and insight; and the events during sessions that connect over time (Block & West, 2013; Coetzer, 2007; Leichsenring et al., 2006). Psychotherapy has been found beneficial for improving awareness, reducing anxiety, depression, and anger (DeHope & Finegan, 1999; Hart et al., 2020; Liu et al., 2002; Rochat et al., 2019). An example of a psychotherapy intervention aimed to reduce anger outbursts will focus on improving emotional expression and recognition through vanishing cues that enable the person to focus their attention on relevant features of faces. It can also include discussions on emotion regulation strategies, relaxation training, repeated exercises, constant feedback, and role-playing to promote the transfer of these skills to daily life (Manolov et al., 2019).

Traditional psychotherapy focuses treatment on the patient's past (Gomez, 1997). However, the common assumption that past behaviors predict future behaviors may not apply to people who sustained TBI and experience cognitive and emotional changes (Ruff, 2013). Bieman-Copland & Dywan, (2000) argued that confrontational strategies, such as education and providing direct and experiential feedback, used in cognitive rehabilitation and psychotherapy may increase agitation and lead individuals to maintain their confabulatory beliefs. The authors recommend a behavioral approach as an alternative.

First-Wave Behavioral Interventions

Behavioral interventions are referred to as the first wave of cognitive-behavioral therapy. Behavioral therapy focuses on changing the associations between the stimulus

and the behavior (Skinner, 1965). Behavioral interventions utilize classical conditioning and operant learning (Ruff, 2013). The behavioral intervention is based on the premise that specific thoughts, emotions, and physiological states lead to dysfunctional behavior, and by eliminating these thoughts or emotions, changes in behavior will occur. Behavioral interventions for adults with a brain injury focus on specific behaviors and aim to increase the frequency of positive behaviors and decrease negative behaviors (Fleming & Ownsworth, 2006; Spence, 1956). The first step in teaching specific behaviors is learning and stabilizing the new behavior, then mastering the behavior, and finally, generalizing the behavior to different contexts and environments (Iddon & Grant, 2013; Ylvisaker et al., 2007). This approach includes various types of reinforcement-based treatments, such as differential reinforcement of other behavior (DRO) and differential reinforcement of incompatible behavior (DRI). A reinforcer is withheld in a DRO procedure and only delivered in the absence of negative behavior. The DRI procedure involves providing a reinforcer for any action that is not compatible with the problem behavior (Zubicaray & Clair, 1998).

The operant learning theory provides a conceptual framework that facilitates understanding of the relationship between behavior and environment while also recognizing the impact of cognitive limitations in developing behavioral disorders and the challenges it imposes on learning (Wong, 2008). Recent reviews have highlighted this approach's success in managing aggression in adults with a brain injury (Bezeau et al., 2004; Fyffe et al., 2004). Behavioral interventions were found beneficial for improving behavioral disorders and reducing the frequency of aggressive and inappropriate sexual

behavior in adults with TBI (Bezeau et al., 2004; Fyffe et al., 2004; Willis & LaVigna, 2003; Ylvisaker et al., 2007). Nevertheless, a more recent systematic review found insufficient evidence to support the use of specific behavioral interventions in treating severe behavioral problems such as reducing inappropriate sexual behavior for individuals with acquired brain injury (Clay et al., 2018).

Practitioners' dissatisfaction with behavioral interventions especially when applied to clients with more complex behavioral disorders gave rise to the second wave of behavior therapy - Cognitive Behavioral Therapy (Beck, 1979, 2019).

Second-Wave Cognitive Behavioral Therapy

Introduced in the 1970s, Cognitive Behavioral Therapy (CBT) is a psychotherapeutic approach formed from the development of behavioral therapy and cognitive therapy (Rothbaum et al., 2000). CBT assigns great importance to thoughts as mediating factors between stimuli and emotional and behavioral reactions. Thinking errors and irrational thinking are considered triggers for the client's reactions. According to this approach, cognitive change eventually leads to emotional relief (Beck, 1979). In CBT, the clients learn to identify their negative behaviors before acting on them and thinking of better action choices. The main component in CBT is cognitive restructuring (CR) in which the individual is taught to examine distorted beliefs through reality testing - selecting tasks that help test out these thoughts' accuracy and replace them with more constructive ones (Bradbury et al., 2008; Khan-Bourne & Brown, 2003).

Hsieh et al. (2012) administered a CBT intervention to two adults with moderate to severe TBI aimed to reduce anxiety. The therapy consisted of psychoeducation

regarding the nature and development of anxiety, slow breathing techniques for managing stress and CR, focusing on identifying, labeling, and modifying unhelpful thoughts. The intervention also included exposure exercises such as role-plays of anxiety-provoking situations and planning real-life exposure experiments. Researchers found CBT useful for improving emotional regulation and reducing mental fatigue, anxiety, depression, and aggression in the TBI population (Bradbury et al., 2008; Hsieh et al., 2012; Iruthayarajah et al., 2018; Rothbaum et al., 2000). Additionally, CBT was found beneficial in the reappraisal of the disability and increased participation within the community (Kangas & McDonald, 2011).

Group-based CBT has been found to have better results than individual CBT through the validation and knowledge that their symptoms are not unique. Furthermore, group CBT participants tend to accept suggestions or criticism from the other participants more willingly than from a therapist; nonetheless, the clinician has a crucial role in promoting participation and managing the group discussion (Prigatano & Klonoff, 1988). Despite the vast number of studies that evaluate CBT's efficiency on the brain injury population, there are limitations to this approach with this population. Cognitive restructuring is a meta-cognitive strategy that is likely to be challenging for individuals with cognitive impairments (Kangas & McDonald, 2011). This process requires individuals simultaneously to hold the thought in their head, seek alternative thoughts, and rationalize in order to generate a more appropriate response. These strategies are particularly difficult to implement for those with cognitive impairments and adaptations are needed to improve the efficacy of this therapy approach

Anson and Ponsford's (2006) study examined how well participants understood and applied principles covered in CBT therapy aimed to improve their emotional adjustment. Only one-third of the participants reported that their understanding and implementation of learned skills had improved, and most participants reported smaller gains or no change at all. Furthermore, as some of the common beliefs people experience after TBI may represent catastrophic events that trigger negative thoughts, reconstructing these thoughts might reduce the individual's perspective of that event and prove unhelpful over more extended periods (Kangas & McDonald, 2011). Another important consideration is that CBT is based on the western assumption that people can recognize and modify their own thinking patterns (Ryle, 2012). However, some studies suggest that the process of examining the origins of thoughts, emotions, and behaviors can be inaccurate and misleading (Ryle, 2012; Wegner, 2002; Wheelahan, 2009).

These shortcomings contributed to the evolution of third-wave cognitive-behavioral interventions, including acceptance, compassion, and mindfulness-based interventions. While the second wave of traditional CBT targets the modifications of thoughts, beliefs, and perceptions, the third wave of interventions aims to facilitate a functional change (Hayes et al., 2006). Therefore, this approach may be more applicable to assist individuals with TBI to re-engage in living a meaningful life, despite their neurological and physical deficits (Kangas & McDonald, 2011).

Third-Wave Interventions

Acceptance and Commitment Therapy

Acceptance and Commitment Therapy (ACT) aims to promote more flexible behavior and thinking patterns that support the individual's values (Wilson & Roberts, 2002). ACT attempts to modify psychological functioning and behavior by changing the relationship between thoughts and feelings to behaviors. According to the ACT approach, psychological inflexibility is a central contributor to emotional disturbances. Psychological flexibility refers to connecting to thoughts and feelings in the present moment and adapting behaviors that serve personal values (Hayes et al., 2011). Psychological flexibility is pursued through psychological processes such as Acceptance, which is an essential principle in ACT. It entails learning to accept both positive and negative feelings and thoughts, particularly regarding events the individual cannot control (Hayes et al., 2006).

In contrast to CBT, ACT does not require complex cognitive processes, such as modifying thoughts and emotions. ACT utilizes concrete methods that distance the individual from his thoughts without engaging in them, such as role-playing, assigning physical attributes such as shape, color, and texture to specific thoughts, role plays, or using visual metaphors (Robinson et al., 2019). ACT is especially appropriate for individuals with TBI as it helps them understand verbal and abstract concepts better by using concrete exercises and delivering information in more than one form (Whiting et al., 2012; Whiting et al., 2017). ACT has shown positive results for decreasing psychological distress and pain tolerance in individuals with TBI (Sander et al., 2010;

Soo et al., 2011; Whiting et al., 2020). Nevertheless, a large multisite randomized controlled trial evaluated ACT versus a psychotherapy approach in veterans with and without TBI, showed no difference between the two interventions (Bomyea et al., 2017).

Compassion-Focused Therapy

According to Compassion-Focused Therapy (CFT) (Gilbert & Plata, 2013), certain emotional processes such as shame and self-criticism, contribute to psychological problems, such as depression and anxiety. It was developed for clients who experience high levels of shame and self-criticism to teach them how to self-soothe (Robinson et al., 2019). This model highlights the importance of developing compassion to activate soothing systems, which support emotional regulation. CFT posits that there are at least three emotion regulation systems: the threat system, the drive system, and the soothing system (Gilbert & Plata, 2013). In CFT, the therapist explains important concepts like compassion and rumination and teaches strategies to approach and alleviate suffering. These include reflecting on behavioral patterns (e.g., avoidances) that may lead to distress; Soothing rhythm breathing focused on finding an internal breathing rhythm, and safe place imagery (Robinson et al., 2019). CFT also includes exercises to raise awareness, for example, noticing when the threat system is activated (Ashworth et al., 2011).

CFT led to significant reductions in anxiety, depression, and self-criticism, and significant increases in kindness and self-warmth in individuals following acquired brain injury (Ashworth et al., 2011, 2015; Shields & Ownsworth, 2013).

Mindfulness-Based Therapy

Mindfulness techniques originate from Buddhist meditation practices and adapted for clinical settings by Jon Kabat-Zinn (1982). Kabat-Zinn defines Mindfulness as paying attention in a particular way: on purpose, in the present moment, and non-judgmentally. Mindfulness-based interventions aim to achieve a mental state of focus on the present moment with non-judgmental awareness; According to this approach, the person can improve his emotional well-being by increasing awareness of how automatic behaviors and reactions can cause emotional distress. Individuals are encouraged to acknowledge and accept their thoughts, sensations, feelings, and surroundings with an open and curious mindset rather than reacting automatically. By focusing on the present, rather than ruminating on the past or worrying about the future, people can cope with stressors that often lead to anxiety or emotional regulation difficulties (Kabat-Zinn, 1982; Robinson et al., 2019).

Mindfulness-Based *Stress Reduction (*MBSR) is the most utilized and researched Mindfulness approach, developed in the 1970s for people with chronic pain and terminal health conditions. The program includes mindfulness meditation, body awareness, movement, and exploration of behavior, thinking, and feeling patterns. Mindfulness-Based Cognitive Therapy (MBCT) is an adaptation of MBSR that incorporates Mindfulness practices as well as CBT techniques (Segal et al., 2004). Both programs have the same basic structure. These programs include eight weekly meetings with an all-day retreat; sessions include psychoeducation, different meditation practices, group discussions, and daily home practices. Participants learn to identify automatic reactions to

difficulty and foster a curious, accepting, and non-judgmental perspective.

Interventions based on Mindfulness are becoming increasingly prevalent, and there is growing evidence for the benefits of these interventions in the brain injury population (Marchand et al., 2021). Researchers have found that mindfulness-based interventions can decrease emotional symptoms, including depression and anxiety, and enhance well-being and quality of life (Bay, 2016; Bédard et al., 2003, 2012; Ozen et al., 2016). These programs were also found to improve emotional regulation, mental fatigue, chronic pain, and insomnia in the TBI population (Azulay & Mott, 2016; Borders et al., 2010; Nassif et al., 2016; Johansson et al., 2015; Ozen et al., 2016).

Summary

This chapter contains a review of evidence regarding current theories and methods addressing cognitive and emotional challenges after a TBI. Evidence suggests that the key ingredients for the most effective interventions include:

- Psychoeducation on the impact of TBI on cognitive abilities and emotional regulation as well as essential concepts such as rumination, compassion, and mindfulness (Block & West, 2013).
- Various Mindfulness meditation techniques, including a focus on the breath or body sensations and movement meditation utilized in mindfulness-based therapy (Alsubaie et al., 2017; Azulay & Mott, 2016; Combs et al., 2018).
- Concrete exercises and methods such as imagining physical features to thoughts, using visual metaphors to explain abstract concepts, and emotional processes as used in ACT (Bomyea et al., 2017; Hayes et al., 2006).

- Practicing mindfulness techniques in different environments and contexts, as recommended in the MultiContext approach, increases awareness and generalization of these practices (Toglia et al., 2010; Toglia, 1991).
- A Group format to improve the sense of validation on common and mutual challenges between group members, including group discussions (Mensenkampff et al., 2015; Prigatano & Klonoff, 1988).

These evidence-based essential and beneficial principles from the presented rehabilitation approaches are implemented in the intervention program described in the following chapter.

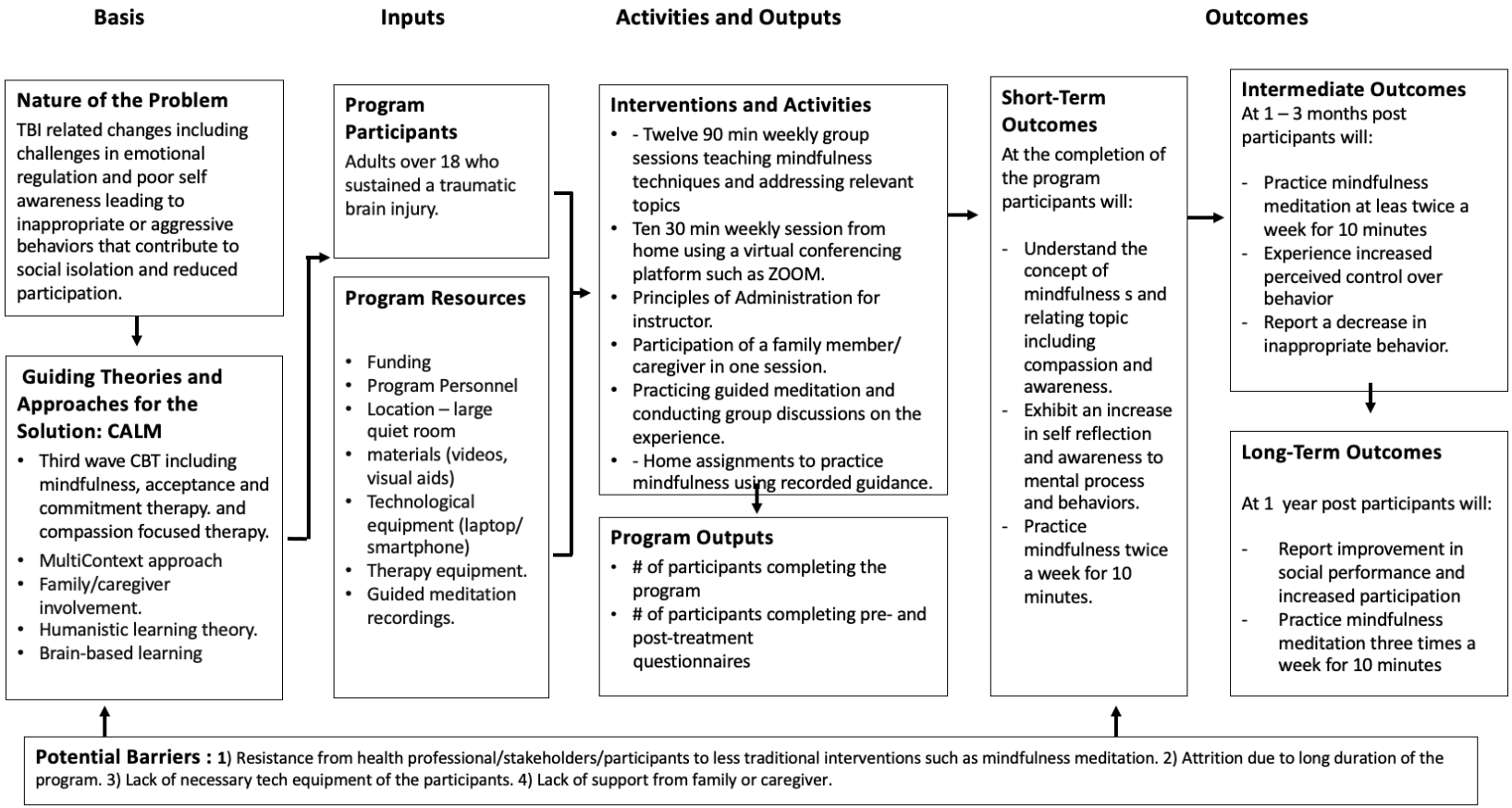
CHAPTER FOUR – Description of the Proposed Program

Introduction

This chapter aims to provide the background, theories, and guidelines for the implementation of a Mindfulness-based occupational intervention designed to improve emotional regulation and increase self-awareness of individuals who sustained a Traumatic Brain Injury (TBI). The goal of the proposed program, Cultivating Awareness by Living Mindfully (CALM) is to teach the participants to practice Mindfulness techniques in everyday activities and interactions. The CALM program incorporates principles from the latest evidence-based therapy approaches and principles designed specifically for individuals who sustained a TBI. Research evidence on methods to enhance learning for the TBI population informed the structure and teaching approaches of each session. A logic model of the proposed program is found in Figure 4.1.

Figure 4.1

Logic Model of Proposed Program



Basis of the Proposed Program

Nature of The Problem

A traumatic brain injury is one of the leading causes for mortality and disability in the United States. National investigations suggest that approximately 5.3 million people live with TBI-related disabilities in the U.S. (Selassie et al., 2008; Zaloshnja et al., 2008). Individuals who sustained a TBI report profound changes in their cognitive, physical, and emotional functions. The effects of a TBI contribute to the individual's inability to control emotions and thus maintain and form social relationships and participate in life events and activities. Coping with extreme behaviors can negatively impact families and caregivers' quality of life (Anderson et al., 2013; Pugh et al., 2018). This wide range of short and long-term outcomes influences the person, their close environment, and the community. The program presented in this chapter aims to address the urgent need to enhance emotional regulation to improve the health and well-being of people with TBI.

Guiding Theories and Approaches for the Proposed Intervention

The CALM program derives from theories and evidence-based practices found useful for individuals who sustained a TBI. First used are a combination of theories that draw from third wave Cognitive-Behavioral Therapy (CBT), including mindfulness, acceptance and commitment therapy, and compassion focused therapy. In addition, the program is based on the MultiContext approach, family and caregiver involvement, and the humanistic learning theory. The construct of the program follows principles of brain-based learning, which include the latest research methods for optimizing the learning

process of individuals with TBI. All are described as follows.

The first-wave of behavioral intervention consists of traditional behavioral therapy including classical conditioning and operant learning (Ruff, 2013). The second wave of behavioral interventions refers to Cognitive Behavioral Therapy (CBT) (Beck, 1979). The CALM program derives mainly from Mindfulness-based therapy, which is considered the third wave. It also utilizes elements from two other third wave approaches, including acceptance and commitment therapy and compassion-focused therapy.

Mindfulness-Based Therapy. Mindfulness techniques originate from eastern Buddhist meditation practices and were originally adapted for clinical settings by John Kabat-Zinn (1982). It is defined as paying attention in a particular way: on purpose, in the present moment, and non-judgmentally. Mindfulness aims to achieve a mental state of focus on the present moment with non-judgmental awareness, improving emotional regulation. Differently from the second wave of traditional CBT which targets the modifications of thoughts, beliefs, and perceptions (Beck, 1979), the third wave of interventions aim to facilitate a functional change (Beck, 2019; Hayes & Hofmann, 2017; Kangas & McDonald, 2011). According to Mindfulness-based approach, the person can improve his emotional well-being by increasing awareness of how automatic behaviors and reactions can cause emotional distress. Clients are encouraged to acknowledge and accept their thoughts, sensations, feelings, and surroundings with an open and curious mindset rather than reacting automatically. By focusing on the present, rather than ruminating on the past or worrying about the future, clients can cope with stressors that often lead to anxiety or emotional regulation difficulties (Kabat-Zinn, 1982; Robinson et

al., 2019). Mindfulness-based programs were also found to improve emotional regulation, mental fatigue, chronic pain, insomnia, and in the TBI population (Azulay & Mott, 2016; Bay, 2016; Combs et al., 2018; Johansson et al., 2015; Ozen et al., 2016).

Mindfulness practice is the key ingredient of the program. Participant will engage in regular practice of Mindfulness meditation and receive home practice activities that are designed to implement these practices to their everyday lives and activities. For example, establishing a morning routine that is performed with a conscious mind, participants are encouraged to focus their attention at the current task such as brushing their teeth or organizing their bed.

Acceptance and Commitment Therapy. Acceptance and Commitment Therapy (ACT) attempts to modify psychological functioning and behavior by changing the relationship between thoughts and feelings to behaviors. According to the ACT approach, psychological inflexibility is a central contributor to emotional disturbances. Psychological flexibility refers to connecting to thoughts and feelings in the present moment and adapting behaviors that serve personal values (Hayes et al., 2011). Activities in the proposed program include exploring and personal value, for example, being a good parent, helping others, supporting my spouse. Psychological flexibility is pursued through psychological processes such as Acceptance, which is an essential principle in ACT. It entails learning to accept both positive and negative feelings and thoughts, particularly regarding events the individual cannot control. (Hayes & Hofmann, 2017). The content of the proposed program includes exploring the concept of acceptance and practicing Mindfulness techniques that improve acceptance. Furthermore, ACT utilizes concrete

methods that distance the individual from his thoughts without engaging in them, such as role-playing, assigning physical attributes such as shape, color, and texture to specific thoughts, role plays, or using visual metaphors (Robinson et al., 2019).

The proposed program includes such concrete methods and discussion on abstract concepts that often related to mindfulness practice through group activities.

Compassion Focused Therapy (CFT). According to Compassion Focused Therapy (Gilbert & Plata, 2013), certain emotional processes such as shame and self-criticism, contribute to psychological problems, such as depression and anxiety. (Robinson et al., 2019). This model highlights the importance of developing compassion to activate soothing systems, which support emotional regulation. In CFT, the therapist explains important concepts like compassion and rumination and teaches strategies to approach and alleviate suffering. Strategies that are used in CFT and implemented in the CALM program include exploration of the concepts self- compassion and compassion for others and understanding rumination. Furthermore, similar to CFT, the Mindfulness-based exercises (such as Mindfulness meditation) implemented in the CALM program are designed to increase self-awareness and activate brain regions that are associated with increased compassion.

The MultiContext Approach. The MultiContext (MC) approach (Toglia et al., 2010)targets transfer and generalization as the therapy program's main goals. These goals are achieved through the practice of metacognitive strategies in different contexts to increase awareness and generalization of those strategies. Tasks and environments are increasingly changed, but the strategy and techniques remain the same. Metacognitive

strategies include anticipation of challenges, outcomes, and appropriate strategy, and self-prediction of necessary performance, which is then compared to self-evaluations after the task. This approach has been found beneficial for improving metacognitive learning, skills generalization, improvement in self-awareness, and self-monitoring for adults post-TBI (Blaker et al., 2020; Doig et al., 2020; T. Ownsworth et al., 2010). Following the principles of Toglia's MultiContext approach (Toglia et al., 2011; Toglia, 1991), the program includes weekly online sessions from home, and exercises to practice these techniques during everyday activities and interactions. These components are designed to increase the transfer and generalization of mindfulness practice to different settings and contexts.

Family / Caregiver Involvement. A family member or a caregiver are requested to attend one program session in order to increase family support in the practice and enhance the benefits of the intervention (Gambrel & Keeling, 2010). Additional principles and modifications to the program, such as extended length, spaced repetitions, and specific guidelines to the administrator, were derived from mindfulness-based programs designed for people who sustained a TBI (Azulay & Mott, 2016; Combs et al., 2018; Johansson et al., 2015).

Humanistic Learning Theory. The holistic view of the humanistic learning theory is suitable for increasing learning with people who sustained a TBI in long-term rehab programs because it is client-centered and designed to increase motivation, self-control, and learning (Braungart et al., 2003; Johnson, 2014). The theory has four main principles that are embedded in the CALM program:

- Motivation – The Humanistic learning theory targets motivation as a significant factor for improving the learning process. In CALM participants are asked to write down the goals they hope to achieve through the program and their personal values. They are encouraged to review these goals at the beginning of each week of the intervention program as to encourage the participants to actively participate and engage in the program.
- Self-Perspective - The theory emphasizes the importance of positive emotions, self-efficacy, and confidence to improve learning and transfer knowledge. The instructor of the CALM program conducts group discussions that are respectful and empowering of each of the members in the group. The program also includes exercises of gratitude which cultivate positive emotions.
- Freedom of Choice - Individuals learn best when they make the choices that guide their education. Individuals with TBI often experience a loss of control over their lives. Encouraging them to make choices and express their desires and emotions can increase their motivation for learning. During the program participants will be exposed to various methods to practice mindfulness meditation, and are invited to practice at home the type that is most appealing to hem
- The Therapeutic Relationship - The therapeutic relationship has an essential part in cultivating motivation and improving learning. The instructor of CALM has a crucial part in facilitating group discussion and engagement. CALM instructors are required for a short training program that emphasizes that provide tools for establishing a solid therapeutic relationship with the group.

Brain-Based Learning. Apart from the various established therapy approaches discussed above, establishing the learner's profile of individuals who sustained a TBI is vital in the success of rehabilitation programs. A learner's profile consists of the methods and approaches that support the optimal learning experience and the acquisition of knowledge. Brain-Based Learning (BBL) refers to education methods that are based on the latest scientific research on how the brain learns best (Jensen, 2008; Ylvisaker et al., 2001). Impairments in memory following TBI are more likely a result of inadequate information acquisition rather than poor retrieval from long-term memory storage. Therefore, interventions focused on improving the quality of learning should improve performance (Hillary et al., 2003). Individuals with TBI often experience attention deficits that negatively impact the learning process; thus, they perform better in a distraction-free environment (Knight et al., 2006). People with TBI require significantly more learning trials than people with no TBI to learn the same amount of information (DeLuca et al., 2000), so repeating important information and practices can improve learning. Furthermore, it has been proven that repetition will facilitate memory and recall more effectively in a spacing format in individuals with TBI (Hillary et al., 2003). When controlling the amount of information acquired during repeated learning trials and spacing between repetitions, individuals who sustained a TBI improve their memory recall and recognize learned information at a level comparable to healthy adults (Hillary et al., 2003).

Individuals with TBI experience difficulties transferring learned skills and strategies to other contexts (Toglia, 1991). During therapy sessions, retrieval practice

improves memory, generalization, and transfer of learned skills to different contexts and environments in individuals who sustained a TBI (Sumowski et al., 2010). Examples of retrieval practice include asking questions about the learned information shortly after discussing it. The questions should be broad questions that encourage thinking and assigning meaning and asking the participants to write down everything they remember from the session (Sumowski et al., 2014). These principles are embedded in the CALM program aiming to support the optimal learning experience of the participants.

Principles of Administration

Principles of administration to guide the instructor of the program are based on recent Mindfulness-based intervention studies conducted with the TBI population.

Ignoring and Reorienting. Impulsivity and disinhibition are common symptoms resulting from severe TBI. During the group, mild behaviors should be ignored to avoid reinforcing these behaviors and maintain focus on the group activity, more offensive/inappropriate comments should be addressed with a redirecting statement: "Rewind 30 seconds and come up with a response that you would have given had you been mindful about what you might say." For participants who struggled with impulsivity, statements such as, "Take a breath before answering" may help. If participants become distracted, the administrator may say: "I'm bringing you back to the moment" (Combs et al., 2018).

Encouragement of Participation. Each group session, all participants should be encouraged, but not required, to speak and share their experiences with mindfulness practice (Combs et al., 2018).

Retrieval Practice. Every session includes asking questions about the learned information shortly after discussing it, and at the beginning and end of each session. The questions should be broad that encourage thinking. The clients will keep a journal and have time to write important notes. This is aimed to improve obtaining learned information and transfer of the learned practices (Sumowski et al., 2010, 2014).

Standard Meditation Instructions. Bring your attention to the primary object of observation. Be aware of it from moment to moment. When you notice that the mind has drifted into thought, bring awareness and consideration back to the present moment. In the body scan meditation, the primary objective is that region of the body through which one is moving at any moment. When a strong feeling or emotion arises, focus your attention on the feeling as it occurs. When it subsides, return to the primary object of observation. Distinguish between observation of the experience, and interpretations of the experience. Observe the thinking process itself. Avoid becoming involved in the content of individual thoughts (Kabbat-Zinn, 1982).

Program Inputs

Program Participants

Each group will include 6-8 adults with TBI. The program's priority population are adults over the age of 18 who sustained a traumatic brain injury. Participants should be in the post-acute phase of rehabilitation (released from hospitalization), and be identified and recruited through rehab programs, veterans' associations, or other community centers. The participants need to commit to the whole intervention program.

Program Resources

Funding. This program has a significant cost advantage and requires minimal funding and mostly dependent on available resources. The location cost depends on available environment resources which include a large room in a rehabilitation center or community center. The cost of learning aids and material can reach 100$. In addition, the instructor will need a laptop to facilitate online sessions.

Program Personnel. The program instructor must be a certified clinical therapist experienced in working with TBI population, familiar with meditation and mindfulness and maintain a personal meditation regime.

Location. The program requires a private room to conduct the sessions. It is preferred to have ample space so participants can practice mindful walking. It is also possible to utilize outdoor space for walking meditation if there are no significant disturbances. Include modifications for physical limitations as necessary.

Informational Materials. Handouts on the program and mindfulness. Headspace videos (from YouTube) and visual aids presenting pictures of meditation practice

Technological Equipment. Smartphone/Laptop- Participants and instructor must have a device where they can listen to the recordings of mindfulness meditation and participate in the at-home group meditation sessions. There needs to be a screen connected to a computer in every session to play the necessary videos.

Guided Meditation Recordings. Six mindfulness meditation recordings are distributed throughout the program.

Therapy Equipment. Whiteboard, individual notebooks and writing tools, materials for mindfulness activities

Program Outputs

Intervention and Activities

The CALM program is partially based on the Mindfulness-based stress reduction program (Kabat-Zinn, 1982). The duration of the program was increased from 9 weeks to 12 weeks in order to accommodate difficulties related to TBI including problems with attention, concentration, and memory (Bédard et al., 2014; Combs et al., 2018). It also includes 10 online sessions from home aimed to increase transfer and generalization of the learned skills (Combs et al., 2018; Toglia & Golisz, 2017). Each session of the program has a similar construct, and sessions topics include Mindfulness, compassion, emotional regulation, acceptance, and more. Each session can be extended over two weeks if needed to cover a topic in more detail or allow for more repetition. The basic outline of the program Sessions is presented in Table 4.1. See a detailed outline of the program plan in Appendix A. Each in-person session begins with a 5–15-minute Mindfulness practice, focused on observing thoughts, emotions, and sensations, and continues with a review of last week's session and home exercises. Following that, the instructor presents the session's topic, conducts a group activity designed to explain abstract concepts associated with Mindfulness and generates a discussion. Furthermore, each session includes watching an information video about the topic of the session, and participants are asked to freely document in a personal journal what they have learned in

this meeting. The sessions are completed with another 5–15-minute Mindfulness practice, and participants receive a home activity for Mindfulness practice. A detailed example of an in-person group session is attached in Appendix B.

Table 4.1

Program Outline

In-Person Session	Online Home Sessions
• 5–10-minute meditation practice • Review last week's topic and homework • Introduce the session's topic • Activities: 5-minute Video and group game • Topic Explanation followed by group discussion • Review of session • 5–10-minute meditation practice.	• 5-minute setup • 10–15-minute practice • Review of this week topic • Share experiences from practice • One minute practice.

Outputs

The program outputs consist of the number of participants completing the program and the number of participants completing pre- and post-treatment questionnaires.

Expected Outcomes

Short-Term Outcomes

At the completion of the program participants will:

- Understand the concept of mindfulness and relating topics including compassion and awareness.
- Exhibit an increase in self-reflection and awareness to mental process and behaviors.
- Practice mindfulness twice a week for 10 minutes.

Intermediate Outcomes

At 1 – 3 months post participants will:

- Practice mindfulness meditation at least twice a week for 10 minutes.
- Experience increased perceived control over behavior.
- Report a decrease in inappropriate behavior.

Long-Term Outcomes

At 1 year post participants will:

- Report improvement in social performance and increased participation.
- Practice mindfulness meditation three times a week for 10 minutes.

The potential barriers for the implementation of the program and possibilities for mitigating them are detailed in Table 4.2

Table 4.2

Potential Barriers and Mitigation

Barriers	Mitigation
Health professionals and stakeholders may oppose the program if they consider mindfulness practice less preferred than other, more traditional interventions.	Relevant professionals and stakeholders will be invited to attend a meeting in which the program is reviewed including supporting data for efficacy and requirements for administration. They will also receive informational written material addressing these aspects.
Possible candidates for the program may also have negative associations with their perception of mindfulness and may refrain from entering the program.	Potential participants in the program will attend a preliminary session in which an explanation on the program construct, duration and required demands, they will also receive a handout with the outline and requirements of the program.
The program's prolonged duration requires a commitment that may be challenging or threatening for individuals with TBI.	In addition to the preliminary session aimed to provide information and establish the requirements. The instructor of the program needs to provide support and guidance to the participants to address their challenges. Participants who need to withdraw will also receive support.
Participation in the program requires operating a laptop or smartphone. Some participants may require assistance from a family member or caregiver, which may not always be available.	A family member and or caregiver will participate in a preliminary meeting explaining the requirement and stressing the importance of their support for the success of the program. Furthermore, they are asked to participate in one of the program sessions to increase their engagement and support.

Summary

This chapter presented an overview of the proposed intervention program aiming to improve the emotional regulation and self-awareness of individuals with TBI. Adults with TBI experience emotional regulation challenges that impact their behavior and social participation. CALM is an evidence-based and theoretically driven mindfulness

program that utilizes principles from third-wave CBT, the MultiContext approach, family involvement, and additional brain-based learning strategies appropriate for individuals who sustained a TBI. It is a low funding 12-week program.

Potential challenges include resistance from stakeholders and participants as well as lack of support from family members or caregivers. These barriers can be mitigated by providing information and adequate preparation before the program and supporting participants during the program. CALM aims to support the acquisition, transfer, and generalization of learned skills to different contexts and interactions, leading to better emotional regulation and increased awareness that contributes to social participation and self-efficacy.

CHAPTER FIVE – Program Evaluation Research Plan

Introduction

This chapter will review the program evaluation plan for Cultivating Awareness by Living Mindfully (CALM) intervention program. The CALM program, designed for adults who sustained a Traumatic Brain Injury (TBI) aims to improve emotional regulation and increase self-awareness. The program utilizes evidence-based approaches designed to make Mindfulness practice accessible for this population and accommodated for TBI related challenges.

The author's program evaluation research will explore efficacy of CALM in improving participants emotional regulation and self-awareness. The evaluation will also examine the content, activities, and delivery of the CALM program. In the short term, the study's findings will establish if the program indeed cultivates positive changes for the participants. Furthermore, it will enable the program's optimization by analyzing feedback on program delivery, the vital components, and the participants' experiences.

In the long term, the evaluation findings will help support the premise that traditional cognitive therapy for individuals with TBI, which mainly focuses on identifying and correcting these negative thoughts, lacks the attention for the clients' state of mind. The findings of this study will provide an evidence-based intervention program for individuals with TBI and increase the tool set of Occupational Therapists (OT) who are working with this population and promote their use of these techniques. Significant findings may also motivate other rehabilitation centers to implement the program in their facilities and potential participants to join the program.

Formative and Summative Evaluation

The research study process includes formative and summative components. The formative evaluation component explores whether the program is operating as planned and examines if the program's delivery, components, and content are feasible, beneficial, and assists in optimizing the program. Information will be gathered following program completion. The qualitative formative evaluation component consists of a survey with open-ended questions to elicit reflections about their satisfaction with the program's content, activities, and delivery (see appendix C). Additionally, participants' experiences and perspectives of the program's content and delivery will be further elicited using focus groups.

The summative evaluation component is aimed at exploring and establishing connections between the intervention and the outcomes by analyzing quantitative numerical data to be collected prior to and following program participation. This section will include standardized measures to evaluate changes in emotional regulation and self-awareness. Since this will be the pilot program, the design will be a quasi-experimental with one intervention group. The evaluation includes a qualitative assessment that is focused on obtaining an in-depth reflective exploration of each participant's process to develop self-awareness during the program of each participant**.**

Plan for Engagement of Stakeholders

The findings of this research will be relevant to several stakeholder groups:

- Potential participants and their families - Positive and significant benefits from the disseminated program evaluation findings will be valuable for potential

participants and encourage them to enroll in the program or request it in their rehabilitation facility. Moreover, partnering with patients and family members is essential for making this study relevant and applicable to them (Black et al, 2018).

- Occupational therapists and health professionals - The findings of this evaluation study are essential for therapists working with the TBI population. Significant results will motivate therapists to implement this program in their workplace, refer their clients to the program or participate in the study.
- Managers of rehabilitation facilities and community centers - These individuals will be interested in a program that may benefit their patients or community members.
- Funding organizations- Such as The Ministry of Defense or the VA that funds and operates many rehabilitation facilities for veterans with TBI and will be interested in implementing a program that can benefit their clients. These organizations can influence the dissemination of the program across the country.

Interested stakeholders will be invited to partake in posing the research questions needed for formative and summative evaluation, collaboratively determine the methods and measures, help with participant recruitment, be involved in data collection and analysis, and participate in the dissemination stage. The author will begin by scheduling meetings with key stakeholders including health professionals, managers of rehab centers and relevant organizations to present the program and research design and encourage them to implement and support the program. In order to ensure the understanding, consensus, and potential collaboration of the program by the stakeholders who are

involved in the study, the author will conduct a preliminary exploration and confirmatory process. First, the author will present the program in a staff meeting that is attended by the participating stakeholders. This meeting is intended to inform, and recruit interested stakeholders to be partners in the intervention and research. The meeting will include a brief literature review of the problem and the traditional approaches to address it, the principles and data supporting the suggested program, the program outline and expected outcomes, a review of the proposed evaluation plan that will be open to changes based on stakeholders' inputs and feedback. The author will encourage questions and suggestions from the stakeholders. The author will emphasize the significance of their contribution and cooperation throughout the program. At the end of the meeting, a document outlining the program and research and each stakeholder's role will be distributed. There will also be a preliminary meeting with the participants of the program and their family member or caregiver in which the program is reviewed, including the requirements for participation and the importance of the family member and caregiver's support to the success of the program. Possible research questions relevant to the stakeholders involved in the program evaluation are listed in Table 5.1. These questions may change based on the responses and feedback from the stakeholders.

Table 5.1

Program Evaluation Research Questions

Stakeholders	Types of Program Evaluation Research Questions
The Author	Qualitative: ● What were the participants' most meaningful activities in the intervention program? ● Did the participants gain an understanding of essential concepts, such as mindfulness and self- reflection? ● Did participants experience the program as beneficial? ● How did the participants perceive the delivery and content of the program? ● What were the challenges and strengths in the delivery of the program? In-person and online. ● Does the program improve self-awareness? Quantitative: ● How much will the program influence emotional regulation? ● How many times did participants practice mindfulness during the month following the completion of the program? ● Will family members or caregivers experience a positive change in participant's behavior?
Potential Clients	Qualitative: ● Will this program help improve my anger outbursts? ● Will this program improve my social relationships? ● Will this program help me feel better? ● Will I succeed in following the activities in the program?
Health Professionals	Qualitative: ● What is the client’s feedback on the program and delivery? ● Did participants and family members or caregivers experience a positive change in awareness? Quantitative: ● Did participants and family members or caregivers experience a change in emotional regulation? (Fewer reports of aggressive behaviors?)

Managers of rehabilitation facilities	Qualitative: ● Was the program meaningful for the participants and their families /caregivers? ● Were there any logistic challenges or requirements? ● Were there any scheduling issues during the program? Quantitative: ● Can the research data demonstrate the desired change in recipients? ● Did the incidence of violent behavior of the participants in the center reduce following the program? ● Will findings show that the course content matches the knowledge needed to close the clinical gap the project addresses?
Funding Organizations	Qualitative: ● Does the content of the program match the presented outline and meet the organization's goals for rehabilitation? ● Are the expected outcomes and objectives of the project realistic and achievable? ● Did recipients of the intervention and family members report a beneficial experience with the care received? ● What are the research requirements? ● Were any problems or issues reported during the program? Quantitative: ● Will the research data show that the intervention led to the desired change in the dependent variables, including emotional regulation? ● Can the research data be used to demonstrate improved quality of care provided to recipients of the intervention? ● What were the rates of attrition?

Method

Research Questions

1. Will the CALM intervention reduce the frequency of inappropriate or aggressive behaviors in adults who sustained a TBI?

2. Will the CALM intervention improve self-awareness in adults who sustained a TBI?
3. Will the CALM mindfulness-based group intervention improve emotional regulation in adults who sustained a TBI?
4. How do family members perceive changes in the participants' behavior and emotional regulation? (Daily behavior checklist)
5. How often do CALM participants use mindfulness in their daily life?

Study Design

To answer the research questions and determine the effectiveness of the CALM program, a Single-Subject Design (SSD) was designed. The purpose of this SSD is to demonstrate a causal relationship between the CALM program and an improvement in self-awareness and emotional regulation. The type of this single-subject design is an A-B-C design.

Participants and Setting

The study will take place at a rehabilitation center for adults with a TBI such as a Veterans Affairs (VA) facility or a community center that provides services to individuals with TBI. Participants will include four to six adults over the age of 18 who sustained a TBI, are at least 1-year post-injury, and experience challenges in self-control and emotional regulation reported by the participants and family members or caregiver. The participants should live in the community with a family member or caregiver. A certain degree of self-awareness is required for the success of the program. This will be

determined by comparing participants' scores on the Patient Competency Rating Scale (Hellebrekers et al., 2017) with those obtained by their family member or caregiver. The participants must have a technology device (i.e., smartphone, tablet, or laptop) that will enable them to participate in the online group meetings from home.

The Intervention - CALM

The CALM intervention program is based on the Mindfulness-Based Stress Reduction program (MBSR) developed by John Kabat-Zinn (1982) that aims to achieve a mental state of focus on the present moment with non-judgmental awareness, improving emotional regulation. The program derives from theories and evidence-based practices found useful for individuals in the post-acute phase of TBI. The program combines elements from cognitive rehabilitation, and third-wave Cognitive Behavioral Therapy (CBT) approaches, including Acceptance and Commitment Therapy (ACT) and Compassion-Focused Therapy (CFT). The MultiContext approach is applied through the practice of learned metacognitive strategies in different contexts to increase their transfer and generalization.

The CALM program utilizes caregiver involvement and other adult learning theories that promote learning for adults with TBI. Participants are introduced and familiarized with various methods to practice meditation and receive homework practice assignments. The CALM program will serve adults over the age of 18 who sustained a TBI. A family member or the primary caregiver will also be included in parts of the program. It is the author's premise that positive changes in emotional regulation of individuals with TBI will benefit the participants, their families, and the community.

The CALM program consists of 12 weekly group meetings, and 10 weekly online sessions from home focused on learning mindfulness techniques and transferring them to everyday activities and interactions. During the program, participants learn essential concepts for practice, including mindfulness, rumination, reflection, compassion, etc. Each session consists of a short and easy to understand explanation using visual aids, a discussion, mindfulness practice, and a homework assignment for practice. The clinician that administers the program must be a certified health professional that is experienced in working with the people who sustained a TBI and maintains personal mindfulness practice regimen. The therapist will follow a detailed program manual to increase the reliability and consistency of the intervention.

Outcome Measures

- The Patient Competency Rating Scale (PCRS) – The PCRS is used to compare participants' self-ratings of competencies to ratings of family members or caregivers (Hellebrekers et al., 2017). This 30-item evaluation assesses competencies in several aspects such as activities of daily living, cognitive functioning, interpersonal functioning, and emotional regulation. Test-retest reliability coefficients ranging from 0.85–0.97 and internal consistency coefficients (Cronbach's) ranging from 0.91–0.95.
- The Overt Behavior Scale (OBS) - (Kelly et al., 2006). The OBS is designed to measure common challenging behaviors observed after a brain injury in community settings. The OBS has 34 items in nine categories that measure aggression, inappropriate sexual behavior, perseveration, wandering,

inappropriate social behavior, and lack of initiation. Inter-rater reliability and stability coefficients for the OBS total score are strong (0.97 and 0.77, respectively). Test–retest reliability is strong (0.77, $p < 0.001$). The OBS has good responsiveness to change demonstrated with a significant decrease in OBS scores in the expected direction over four months (Kelly et al., 2006).

- The Difficulties in Emotion Regulation Scale - (DERS) - The DERS is used to evaluate emotional regulation. It is a widely used self-report measure of subjective emotion ability. Internal consistency above 0.80 (Hallion et al., 2018).
- The Five Facet Mindfulness Questionnaire -(FFMQ) - is a self-completed questionnaire measuring the five facets of mindfulness: Observing, Describing, Acting with awareness, Non-judgmental, and Non-reactive. For this study, the 24-item shorter version by Bohlmeijer et al. (2011) will be used as it is the most widely used form with the best psychometric properties.
- Survey - Including several close-end questions using a 5-point Likert scale (how much do you agree?) and address the participants' experience in the program addressing the content, activities, delivery (Appendix C.).
- The Daily Behavior Checklist- developed by the author that participants will fill out during the study to indicate changes in anger outbursts or problematic behaviors (Appendix D).
- Focus group at completion of the program to provide a formative and summative evaluation of the intervention and support its optimization (Appendix E).

Procedure

The CALM program evaluation research will include three step mixed methods design which includes a pre-post quasi experimental design together with a single subject design.

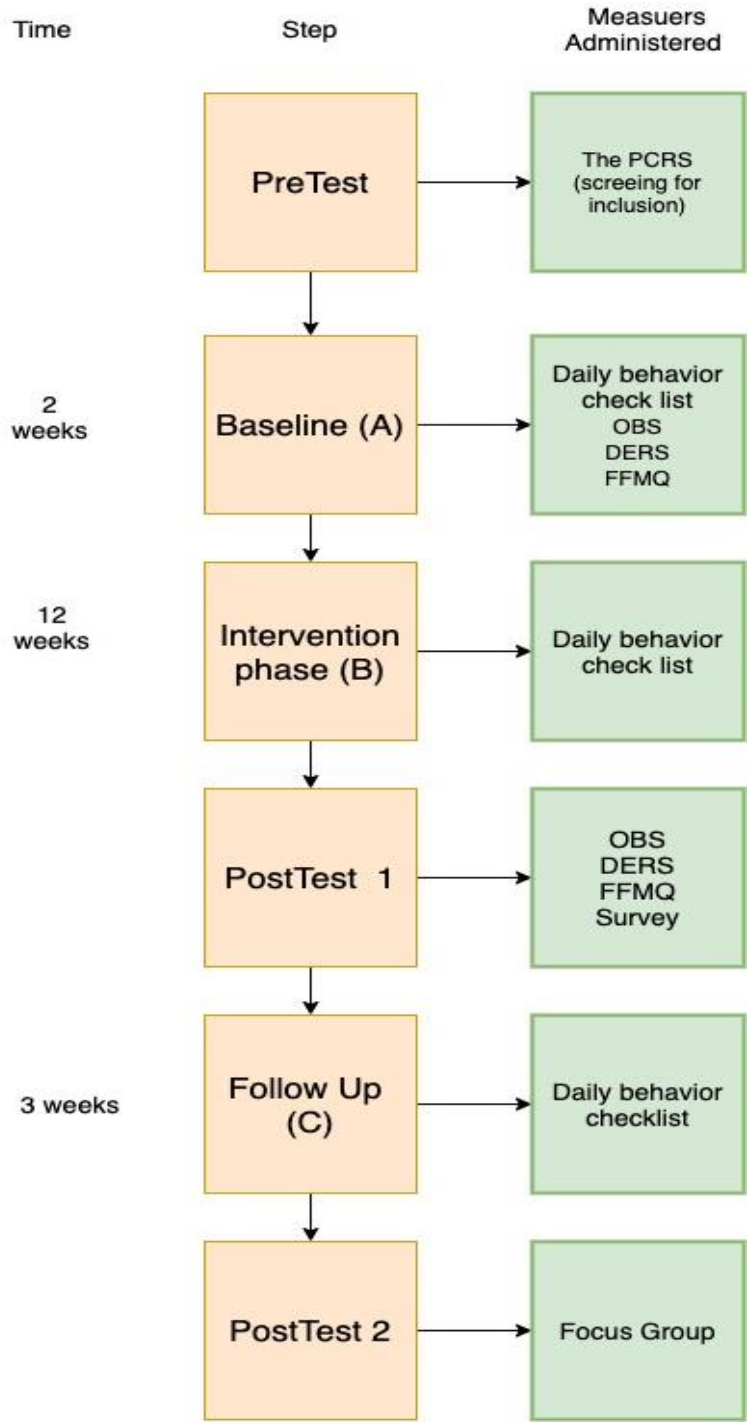
The sequence and duration of each stage will be as followed:

- Pre-Test Phase – The Patient Competency Rating Scale is administered to determine the required level of awareness for inclusion of potential participants.
- A - Baseline Phase -lasting two weeks. In this phase, data will be collected daily by the participants and a family member/caregiver to establish a stable baseline using the daily behavior checklist. The OBS examining problematic behavior, the DERS measuring emotional regulation changes and the FFMQ measuring mindfulness will be administered at the end of phase A.
- B - Intervention Phase – lasting 12 weeks. In this phase, the intervention is conducted, the participants and family members/caregivers continue to fill the daily behavior check sheet.
- Post-Test 1 Phase – The post-test evaluations are conducted at the completion of the program and include the OBS, DERS and FFMQ. Participants receive a survey with questions concerning their experience during the program and their feedback.
- C - Follow Up Phase – lasting three weeks. Participants and family members/caregivers continue to fill the behavior check sheet.
- Post-Test 2 Phase – after the follow up phase participants are invited for a 90-min

focus group that explores their experience from the program.

Figure 5.1

The Evaluation Process



Ethical Considerations

The author will obtain the Institutional Review Board (IRB) approval. To achieve their consent, the author will ensure the confidentiality of the participants by requesting the individuals involved in the program to sign a confidentiality agreement not to disclose any information regarding the program or the participants. Furthermore, the author will secure all the data collected using passwords or in locked file drawers, and each participant will receive an identification code used throughout the program. The author will not publish any information about the participants that may influence their anonymity.

Data Collection

The data collection will be conducted by the author and a research assistant that will gather qualitative data from the participants to reduce the risk of bias. The evaluation of expected outcomes is performed using standardized quantitative measures to increase the results' reliability. All of which have been used with the TBI population.

Data Analysis

The analysis of the data is performed in several methods. The focus group sessions with the participants will be recorded. The author will analyze the data from the recordings for essential themes that arise and can help optimize the program. The researchers will utilize the traditional approaches for theme analysis of focus groups. The data collected from the results on the outcome measures will be analyzed in the statistical analysis SPSS program. The researchers will conduct a descriptive analysis for

summarizing variables and inferential analyses to establish the degree of change in dependent variables from pre to post program participation. The data analysis will follow the algorithm for analysis of data from an SSD.

Experimental Controls and Internal Validity

It is essential to ensure the fidelity of treatment delivery so that intervention results can be attributed to the program (Frank et al., 2008). The intervention program is based on established theoretical frameworks, and the clinician who administers the program goes through comprehensive training and follows a precise and detailed program manual. The OBS has been chosen in order to decrease repeat testing threat on internal validity, which has strong test-retest reliability and good responsiveness to change. Data collection is performed by the participants and a significant other or caregiver which can reduce the data's reliability and burden the respondents. Therefore, the author will schedule a meeting with the participating individuals to emphasize the importance of being consistent and reliable with the reports they provide. I will include examples of documentation and guidelines for challenges that may occur during data collection. Moreover, the daily behavior checklist is simple to use and requires up to five minutes a day.

An important consideration is the span of the study. Although designed for people with memory difficulties, the study's long duration may lead to attrition or decrease reports' consistency. A thorough yet easy to follow explanation of the research and the participants' requirements, including a discussion of expectations and possible challenges, may help reduce attrition and increase engagement. Furthermore, the observers

(participants and family members) will receive a brief training on the daily behavior checklist they will use to document the problem behavior.

Fidelity to receipt of treatment can be achieved by establishing strategies to ensure that participants can comprehend and use the learned skills as instructed during the intervention (Frank et al., 2008). Therefore, participants are screened for a required degree of self-awareness to increase the effectiveness of the intervention.

Participants in the program may be influenced by the reflective questions posed as part of the measurement. While this is anticipated to have a positive impact, it may accelerate the change process, compared to individuals who participate in the CALM program but not in the study.

Furthermore, interference due to multiple treatments may occur. Participants in the study are requested to not take part in additional cognitive or emotional rehab programs, Nevertheless, they may continue their private therapy sessions, which may have an impact on expected outcomes.

Summary

This chapter presents an evaluation plan for CALM, an intervention program to improve emotional regulation and increase awareness of adults after a TBI. The evaluation plan aims to measure changes in the frequency of inappropriate or aggressive behaviors, self-awareness, and emotional regulation as reported by program participants and their family members. Also assessed is participants' use of mindfulness in their daily life and overall satisfaction and sense of change.

The plan outlines formative and summative components for consideration, and a

plan for stakeholder engagement. The formative data which can help modify and improve the program. The summative data will allow us to establish a correlation between CALM and expected outcomes. Measures include standardized tests, Likert scale survey, checklist, and focus group to measure the range of possible changes.

In this chapter, I focus on a first step in the summative assessment: the execution of a single-subject design study. The consideration for participants and the setting, study design, outcome measures, data analysis and mitigating risks are discussed.

It is my hope that the results of this study establish the benefits of CALM and its contributions to participants' Mindfulness trait, resulting in improved emotional regulation and well-being. Future studies should include a control group that is compared to the intervention group and a larger sample size to increase the generalizability of the findings to the population. The evaluation program presented in this chapter is designed to explore a clinical group intervention program, entitled cultivating awareness by living mindfully. The following chapter will address the dissemination plan for the CALM intervention.

CHAPTER SIX – Dissemination Plan

Introduction

Cultivate Awareness by Living Mindfully (CALM), is a Mindfulness-based group intervention designed to increase self-awareness and improve emotional regulation of individuals who sustained a Traumatic Brain Injury (TBI) by learning to utilize mindfulness techniques in everyday activities and interactions. CALM is an evidence-based and theoretically driven Mindfulness program that utilizes principles from various rehabilitation approaches that support optimal learning for individuals with TBI. CALM is a 12-week program. Each week includes an in-person group session, followed by an online group practice delivered in the persons' home. Each in-person session begins with a 5–15-minute Mindfulness practice, focused on observing thoughts, emotions, and sensations, and continues with a review of last week's session and home exercises. Following that, the instructor presents the session's topic, conducts a group activity designed to explain abstract concepts associated with Mindfulness and generates a discussion. Furthermore, each session includes watching an information video about the topic of the session, and participants are asked to freely document in a personal journal what they have learned in this meeting. The sessions are completed with another 5–15-minute Mindfulness practice, and participants receive a home activity for Mindfulness practice.

Dissemination Goals

The CALM program is meant to be disseminated in Israel and in the U.S. among rehabilitation and community centers. The dissemination goals include short-term and

long-term goals.

Long-Term Goal

The dissemination of the CALM intervention program will lead to the implementation of the program in rehabilitation facilities in Israel and the U.S.

Short-Term Goals

Present a new evidence-based intervention program for adults who sustained a TBI among potential participants and their family.

Establish relationships with leading figures at government offices in charge of rehabilitation for adults with TBI.

Primary Target Audience

The primary target audience for this dissemination plan are decision makers in the Ministry of Defense in Israel and the Department of Veterans Affairs (VA) organization in the U.S. Both organizations manage, operate, and refer veterans with TBI to rehabilitation centers. These establishments have the power to implement and disseminate the CALM program at many rehab centers and provide the resources needed to maintain this program.

Secondary Target Audience

The secondary target audience for the dissemination plan is adults who sustained a TBI and their family members. This group is the main beneficiary from the program and can increase the demand for this program among insurance companies or at their rehabilitation centers.

Quaternary Target Audience

A third group of audience I would address my dissemination effort are healthcare professionals. These professionals can be coached by the developer to implement the program in their own setting, engage in research, as well as support the dissemination of the program to their clients.

Key Messages for Primary Audience

- The CALM program is a low-cost, evidence-based program that improves functioning and wellbeing of people with TBI and reduces the cost of care in the long-term. It requires few resources and can be implemented in almost any setting.
- The evaluation study of the CALM intervention program showed significant improvements in functioning and wellbeing with positive feedback from participants and their family members.

Key Messages for Secondary Audience

- The CALM program was found beneficial for improving emotional regulation, increasing self-awareness, and improving social functioning and anger management.
- The program is based on methods and approaches that have been found beneficial for people with TBI. It is designed especially for the challenges people with TBI cope with such as memory and attention difficulties.

Key Messages for Quaternary Audience

- The CALM intervention program is an evidence-based program that can support clients with TBI to improve their emotional regulation and rehabilitation outcomes. It follows a manual and can be administered by a health professional who completed a specific training.

Spokespersons for Primary Audience

As part of my work at the rehabilitation center for veterans who sustained a TBI, I am familiar with people in leading positions at the injured veterans wing of the ministry of defense. In Israel, a meeting will be requested with the head of the rehabilitation wing in the office to present the program and the research study conducted on the program. Having the author present the program would be the best approach to accurately deliver the information and message. Regarding the dissemination in the U.S. through the VA I would hope to present the information myself by requesting a virtual or in person meeting with leading personnel in the organization that manage rehabilitation centers for veterans with TBI, and perhaps utilize my contact in Israel's rehabilitation wing to contact it's parallel in the U.S.

Spokespersons for Secondary Audience

The messengers for the second group would be adults with TBI who participated in the program and their family members that can attest to the benefits they have experienced from it. I believe they will be able to deliver the message in the most authentic and powerful way to other individuals with TBI and their family members. This message can be delivered through personal or virtual lectures in rehabilitation centers as

well as recorded testimonies in the CALM program website.

Spokespersons for Quaternary Audience

The messenger for this group should be delivered by the developer or other healthcare professionals that are familiar with CALM or completed the training for administering the program. This group requires a more professional approach through scholarly presentations such as AOTA presentation, OT practice magazine publication, and possibly a research manuscript.

The dissemination activities, timing and budget is detailed in Table 6.1.

Table 6.1

Dissemination Activities, Timing and Budget

	Target Audience	Activity	Description	Related costs	Total Cost
Primary Audience	Israel's Ministry of Defense officials at rehabilitation wing/ The VA in charge of rehabilitation programs, re-habilitation, and community centers	1. Electronic media	The developer will send an introduction email presenting the program and requesting a meeting/ request a meeting through colleagues at the rehabilitation wing in Israel.	$0	$0
		2. In-person or virtual presentation by the developer of the program	The developer will present a PowerPoint containing details about the program, expected outcomes, needed resources, and cost.	Transportation to meetings or	$20
		3. In person and via email	The developer will distribute informational handouts on the program containing details about the program, expected outcomes, and contact information.	Handout copies	$20

Secondary Audience	Adults with TBI in the post-acute phase and family members	1. Written information	Distribute handouts with details about the program and contact information to community centers and rehabilitation facilities.	Transportation to rehabilitation centers and community centers for distribution. 20$ Handout copies 30$	$50
		2. In-person meeting	The developer of the program will approach community centers to request a presentation of the research study on the program.		$0
		3. Electronic media	The developer will upload a video posted on YouTube presenting the program and outcomes of research and distribute the link through relevant social media links.	Video editing- performed by the developer at no cost.	$0
Quaternary Audience	Healthcare professionals	1. Conference presentations	The developer will present the CALM program at relevant conferences such as WFOT, AOTA, ISOT.	Participation Cost	$50-$300
		2. Publish in healthcare and OT magazines.	The developer will submit Abstract for publications on the CALM program for healthcare magazines.		$0
All Target Groups		Electronic media	The developer will distribute a link to the program's website containing all the information about the program and research results, and contact information.	The developer has a connection at WIX.com (website platform), so no fee for domain	$0
	Total cost				$140-$390

Evaluation of the Dissemination Plan

In order to evaluate the success of the dissemination plan the SMART model of determining a specific, measurable, attainable, relevant and time-bound criteria will be utilized.

Evaluation of Dissemination Plan for Primary Audience

The criteria for the success of the dissemination plan of the CALM program with the primary audience will be signing an agreement to implement the program in 4 rehabilitation facilities or community centers by June 1st, 2022.

Evaluation of Dissemination Plan for Secondary Audience

The criteria for the success of the dissemination plan for the secondary audience will not be the number of people signing for the course as the goal for this part of the plan is to get as many people aware of the program. Therefore, the criteria will be 50 people contacting to receive information about the program by March 1st, 2022.

Evaluation of Dissemination Plan for Quaternary Audience

The criteria for the success of the dissemination plan of the CALM program with the primary audience will be presenting in four conferences by the end of 2022 and publishing in at least two healthcare magazines by the end of 2022.

Summary

This chapter outlined the milestones in the dissemination process of the CALM intervention program including the short- and long-term goals, the primary, secondary, and quaternary audience for the dissemination, key messages for each audience, the dissemination activities, timing and budget, the messengers, and the evaluation criteria of

the dissemination plan. The goals of this dissemination plan include contact with leading figures of the related government organizations that can help implement the program in rehabilitation facilities. Additionally, the goal is to reach as many potential participants and health professionals with information about the program. This marketing plan is low-cost requiring funding in the amount of $140 – $390.

CHAPTER SEVEN – Funding Plan

Introduction

Traumatic brain injury (TBI) is defined as a disruption to the brain's normal function, caused by a bump, blow, or jolt to the head (DCD, 2017). TBI is one of the leading causes of disability and death, and therefore poses a significant public health concern with loss of economic productivity and increased healthcare utilization. Common emotional changes after TBI include anger outbursts, physical aggression, low self-awareness, impulsivity, rumination, depression, and anxiety (Hoofien et al., 2001; Tam et al., 2015; Toglia & Golisz, 2017). The effects of a TBI contribute to the individual's inability to control emotions and thus maintain and form social relationships and participate in life events and activities (Manolov et al., 2019; Mateer & Sira, 2006; Toglia & Golisz, 2017).

Cultivate Awareness by Living Mindfully (CALM) is a Mindfulness-based group intervention for adults who sustained a TBI. It is designed to implement Mindfulness techniques into everyday activities and interactions, and thus increase self-awareness and improve emotional. CALM is an evidence-based and theoretically driven mindfulness program that utilizes principles from various rehabilitation approaches that support learning for individuals with TBI. CALM is based on a combination of theories that draw from third wave Cognitive- Behavioral Therapy (CBT), including mindfulness (Kabat-Zinn, 1982), Acceptance and Commitment Therapy (Hayes et al., 2006), and Compassion Focused Therapy (Ashworth et al., 2011). In addition, the program is based on the MultiContext approach (Toglia, 1991), family and caregiver involvement, the humanistic

learning theory (Johnson, 2014), and brain-based learning. CALM aims to support the acquisition, transfer, and generalization of learned mindfulness skills to different contexts and interactions. Each session begins with 5–15-minute Mindfulness practice and continues with a review of last week's session and home activities. Following that, the instructor presents the session's topic along with a group activity designed to explain abstract concepts associated with Mindfulness and trigger a discussion. Furthermore, each session includes watching an information video about the topic of the session, and participants are asked to freely document in a personal journal what they have learned in this meeting. Each session is completed with another 5–15-minute Mindfulness practice, and participants receive a home activity for practice.

Available Resources

The developer of the program is the instructor and will administer the program at no cost during the initial pilot study of the program. Moreover, the Mindfulness community is an international group, eager to spread knowledge, teach, and support the dissemination of mindfulness. In most cases this is done as volunteer work. There are several mindfulness teachers who have expressed their desire to support the optimization of the CALM program, provide feedback and knowledge that can support the program. Furthermore, community and rehabilitation centers, such as "Margoza", The rehabilitation center for Israeli veterans, expressed interest in implementing the program in their facility. The center can provide a physical venue for group meetings.

Needed Resources

The CALM intervention consists of 12 in-person meetings and 10 home-based online meetings. The first program will be a pilot study aimed to examine the impact of the intervention and will require a research assistant to help with assessment and data analysis. The instructor will not receive payment in the pilot study so the cost of the program will be up to $1580 for the location and materials. After that, the program will run with a cost of 100$ per week for the instructor. Expenses for the program require an initial purchase of therapy equipment at the cost of $100 and each group requires additional cost of photocopy of handouts to participants and family in the amount of $20 and unexpected cost of supply such as pens, and notebooks can reach $100. The location for the program may be provided free by the paying establishment or rented location at a monthly cost of $150 per group. Table 7.1 presents the budget for the pilot study group program and a yearly budget for four consecutive regular groups.

Table 7.1

CALM - Yearly Budget Plan

Category	Description	Cost - 1 Pilot Group	Yearly Budget - 4 consecutive groups
Personnel	Instructor The first program will be the pilot study and the developer who is the instructor will not receive payment. After that, the program will run at a cost of 100$ per week for the instructor. A total $1200 per group Research Assistant The research assistant supporting the pilot study through data collection and analysis, will receive a monthly salary of 80$ per week. Total of $960 for the pilot group alone.	$960	$4,800
Consultants	Consultants and any additional support will be on a volunteer basis.	$0	$0
Materials preparation	The author will develop the materials with no cost to the work	$0	$0
Technological Equipment	Participants must own a laptop or smartphone to enable participation in the online group sessions.	$0	$0
Informational Materials	Handouts on the program and mindfulness	$20	$80
Instructional equipment	Whiteboard, individual notebooks and writing tools, materials for activities including large metal disk, fabrics, Tibetan bowl, mirror. Use of headspace videos- Free	$100	$400
Rental of facilities	May be provided by the paying establishment at o cost or rented at a monthly cost of $150 per group X 3 month	$450	$1,800
Promotion	Handouts will be distributed in rehabilitation facilities and community centers. Additional promotion will be done free of charge through social media.	$50	$200
Evaluation	The DERS- free The Overt Behavior Scale- free The Five Facet Mindfulness Questionnaire - free	$0	$0
Total		$1,580	$7,280

Potential Funding Resources

Facilities that are interested in implementing the program in their establishments pay for the program choosing from charging clients fee for service or receiving reimbursement from insurance companies. Payment will be received on a monthly schedule but agreed by contract to include the entire duration of the program. The reliability of income is dependent on the number of facilities that are willing to pay for this service and their desire to prolong the service beyond the first three-month program. Furthermore, there are associations and programs that may support with funding to this type of intervention such as:

- The Division of Mental Health, Developmental Disabilities and Substance Abuse Services
- TBI Grant- This is a highly competitive grant which requires a comprehensive research team and design. They provide a total of $ 450,000. https://files.nc.gov/ncdhhs/documents/files/TBIOverview1-2019.pdf
- The Administration of Community Living (ACL) provides funding for rehabilitation programs for adults who sustained a TBI. https://acl.gov/news-and-events/acl-blog/new-grants-announced-traumatic-brain-injury-state-partnership-program
- The Brain Injury Association of America awards Dissertation grants of up to $5,000 total for up to two years for papers that focus on the TBI population. Two awards may be made annually. https://www.biausa.org/professionals/research/grants/dissertation-grants

Summary

This chapter reviews the funding plan for the CALM intervention program. CALM was developed to be a low-cost program that can be implemented in many settings so it can benefit as many people as possible. The cost of funding CALM requires the amount of approximately $1,500 for a 3-month group program, which includes 6-8 participants. Funding for the program can be done via insurance coverage, paid out of pocket, invested by a hosting rehabilitation center or community facility, or by a grant for health services targeting the TBI population which provides funding for rehabilitation programs for adults who sustained a TBI. Healthcare professionals, administrator's and organization's support in CALM will establish this evidence-based intervention program as beneficial for people with TBI.

CHAPTER EIGHT – Conclusion

Introduction

This doctoral paper presented Cultivating Awareness by Living Mindfully (CALM), a rehabilitation program for adults who sustained a traumatic brain injury. The project included a thorough understanding of the impact of the problem, focusing on TBI-related challenges in emotional regulation, and their impact on the person's life and environment. The project also included a systematic evaluation of all existing solutions for this problem and devising a unique program based on the most effective ingredients to address these challenges. The proposed CALM program aims to make Mindfulness practice and its associated benefits accessible for individuals with TBI. This is done by incorporating occupational frameworks and methods that are based on the latest research for optimizing learning and increasing generalization of skills in this population group.

The International Classification of Function, Disability, and Health (ICF) was chosen to present how changes in body functions and structures resulting from a TBI include cognitive, emotional, and physical manifestations. People with TBI experience difficulties regulating emotions, leading to anger outbursts, impulsivity, aggression, and poor self-awareness (Buckley et al., 2017; Seel et al., 2003; Winter et al., 2018). Moreover, people who sustained a TBI often report anxiety and depression, anhedonia, and low self-esteem, which contribute to the person's social isolation (Seel et al., 2003). Cognitive and emotional changes coupled with TBI related physical limitations, frequently result in conflicts with the social environment, and struggles to reintegrate into the community (Fleming et al., 2014; Mahar & Fraser, 2011)**.** The proposed program

aims to address challenges in emotional regulation and their impact on the person's life.

While current therapy approaches, such as traditional cognitive and psychotherapy, pharmacotherapy, and cognitive behavioral therapy, have been beneficial for some of these challenges, extensive evidence shows that challenges in emotional regulation are not effectively addressed (Cicerone et al., 2011; Gómez-de-Regil et al., 2019; Lee, 2019; Oddo et al., 2016). These therapy approaches often focus on identifying and correcting negative thoughts, which can be misleading or ineffective in supporting the transfer of learned skills outside of the clinician's office, leading the client to exhibit the problematic behaviors in other settings such as the home environment.

Different from these standard therapy approaches that address cognitive and emotional challenges, Mindfulness-based therapy is an approach that helps create a willingness to improve, change, and maintain behaviors and patterns of thinking (Kuboy, 2015). By focusing on the present, and not persistently reflecting on the past or future, people can cope with stressful situations that often lead to anxiety or emotional regulation difficulties (Kabat-Zinn, 1982; Robinson et al., 2019). Nevertheless, the standard Mindfulness interventions available for adults with TBI do not accommodate for the specific challenges these individuals cope with, making it inaccessible for them to participate in this type of interventions (Combs et al., 2018; Kristofersson et al., 2016). The CALM program is designed to accommodate for TBI-related challenges, such as memory and attention difficulties and support the transfer and generalization of these skills to contexts outside of the therapy room. The CALM program aims to support the acquisition, transfer, and generalization of learned Mindfulness skills to different contexts

and interactions, leading to better emotional regulation and increased awareness contributing to improved well-being and increased participation in all aspects of life.

Importance of evaluating the CALM program

The evaluation plan for CALM aims to measure changes in the frequency of inappropriate or aggressive behaviors, self-awareness, and emotional regulation as reported by program participants and their family members. Also assessed are participants' use of mindfulness in their daily life and overall satisfaction with the program, and sense of change. This study's results will establish the benefits of CALM and its contributions to participants' mindfulness and resulting emotional regulation and well-being. It is my hope that the findings of this evaluation study will be disseminated in professional conferences and journals, and to potential clients, thus informing future services for the TBI population as well as policy evaluation for rehabilitation services.

Dissemination of CALM

The goals of the dissemination plan for CALM include contact with leading figures of the related government organizations that can help implement the program in rehabilitation facilities. Additionally, the goal is to reach potential participants and health professionals to share information about the program and its associated benefits. These connections will be achieved through different means including conference and journal presentation, in-person meetings, handouts, social media and more. The dissemination of CALM will support the rehabilitation process of people with TBI and establish occupational therapists’ necessity in rehabilitation settings for this population group. Furthermore, the dissemination of CALM supports the utilization and modifications of

Mindfulness-based interventions for people with disabilities or from marginalized groups that cannot access or participate in mainstream Mindfulness interventions. The dissemination of the CALM program consists of several target audiences, key messages and actions that can support in implementation of an evidence-based intervention program for people with TBI.

Funding of CALM

The CALM program is a low-cost rehabilitation intervention requiring few resources to make it feasible for implementation in a variety of health or community settings. The developer of the program will administer the program at no cost during the initial pilot study of the program. After that, the program can be funded by insurance coverage, paid out of pocket, invested by a hosting rehabilitation center or community facility, or by a grant for health services targeting the TBI population.

Reflections and Future Directions

This project provides a detailed intervention program for adults with TBI that can be implemented in almost any setting. The CALM program aims to address the gap in traditional rehabilitation settings for this population which often provide ineffective interventions for emotional regulation and self-awareness. The occupational therapy profession is broad and holistic. It enables the therapist to observe the client's health according to their own perception and views on their health and well-being. Furthermore, it promotes a unique analysis of limiting factors and enables creative ways to address them. This doctoral project aims to address the participants' state of mind to improve emotional regulation. The program is based on a combination of theories, including an

eastern approach (Mindfulness) and western approaches (MultiContext and Brain-based learning) that make Mindfulness practice and its associated health benefits accessible for the TBI population. In the process of developing this program, I have gained confidence in the importance of making Mindfulness practice accessible for people with TBI, specifically for other population groups that cannot participate in standard Mindfulness interventions. My goals for future practices include establishing a course for therapists interested in implementing Mindfulness interventions with their clients, including basic guidelines and accommodations for different population groups. I hope to establish a weekly meditation group (Sangha) for people with cognitive challenges to integrate mindfulness into everyday life, and a group for therapists. Another goal is to modify the CALM program to accommodate older adults with mild cognitive impairments. I would also like to transform CALM into a virtual intervention that can be delivered entirely from home to meet the current challenges of COVID19 and provide this service for people who are isolated or unable to participate in person. Finally, I hope to succeed in disseminating Mindfulness practice and making it accessible to broad populations for them to harness the benefits and enhance their emotional health and wellness.

APPENDIX A.

The Outline of the Program

Topic	Content & Activities
Week 1 **Introduction** **Mindfulness**	**Welcome**- Therapists present their name, experience. Participants are encouraged to introduce themselves and their challenges **Review Group guidelines** and keep them visible during the course. **Explanation** of the program, mindfulness meditation, and associated benefits, and how regular practice can increase self-control and relieve emotional stress. **Discussion** - why do you want to learn mindfulness? **Mindfulness practice** - 5 minutes - focus on the breath. **Homework:** practice for five minutes one time this week. **Ongoing request**: record any observations or questions that arise during the week.
Week 2 **Being Present**	**8-minute practice**- Focus on the sounds. **Review**- Last week, key terms and home practice **Activity**- play video "Understanding Dark Thoughts" **Explain** about the default mode network (DMN) and The connection between rumination and well being **Activity** - group exercise declutters the mind-(oval plate placed on table represents the mind, in the middle there is a stone that represents the focus on the present moment. Participants are asked to think of thoughts they have during the day- and these are represented as different objects thrown on the oval plate until they cover the stone and leave no empty space. **Discussion** -About the activity, How to recognize a cluttered mind. How to clear the mind. **5 minutes practice** - Focus on the breath. **Home activity:** Try to practice for 5 minutes two times this week. **Online home session:** 10 minute practice, brief review of this week's topic and end with one minute of meditation.
Week 3	**10-minute practice**- Focus on body sensations. **Review**- How was your week? what did we discuss in the

Emotional Regulation	**Activity** - play video "Accepting the Mind" **Discussion -** Brief review of mental fatigue, open talk of challenges. Provide a specific example of how mindfulness can help mental fatigue. **5-minute practice** - open awareness. **Homework:** practice for 10 minutes three times this week. **Online session:** 10 minute practice, brief review of this week's topic and end with one minute of meditation.
Week 4 **Attention** **Automatic vs. Awareness**	**5- minute practice-** Focus on the breath. **Review**- last week, content, key terms, and home exercises. **Activity** - Play "The hole in the road" video **Discussion -** Brief review of attention skills, open talk of personal or known attention challenges. Explain automatic vs aware functioning. Provide a specific example of how mindfulness can help attention difficulties. **7-minutes practice** - focus on the sounds. H**omework:** practice for five minutes three times this week. Tip: setting a regular place and time for practice can help. **Online session:** 10 minute practice, brief review of this week's topic and end with one minute of meditation.
Week 5 **Self-Reflection & Compassion**	**12-minute practice-** Mountain meditation. **Review** last week and home exercises. **Activity** - video "Changing Perspective" **Discussion -** encourage participants to reflect with compassion on their emotional responses and thought patterns as a tool for controlling their behavior. guide participants to view the thoughts during practice as floating clouds that come and go and do not always reflect reality. **5-minute practice** - open awareness. **Homework -** practice for 10 minutes three times this week. **Online session:** 10 minute practice, brief review of this week's topic and end with one minute of meditation.
Week 6 **Family Members**	**12-minute practice-** Focus on the breath **Introduction** - welcome family members to the group. **Activity** - play Shared Human Condition

	Discussion- participants explain to S.O. what is mindfulness, and the goals and benefits of the practice. open discussion what promotes a mindful state, how does it impact interaction? ideas to increase home practice. Mutual practice and support **5-minute practice** - open awareness. **Homework-** practice three times this week. Try practicing with S.O **Online session:** 10 minute practice, brief review of this week's topic and end with one minute of meditation.
Week 7 **Mindfulness**	**7-minute practice-** Focus on the breath. **Review**- last week, key terms and home exercises. **Activity** - play video "Training the Monkey Mind" **Discussion -** How to implement mindfulness in everyday activities? address challenges that arise during practice. organizing and planning the practice. **12-minute practice** - walking meditation or body sensation. **Homework -** practice one mindful activity all week- brushing teeth, shower, eating, and 10-minute practice. **Home session** - online 30-minute session including a 15-minute mutual practice of body sensations. **Online session:** 10 minute practice, brief review of this week's topic and end with one minute of meditation.
Week 8 **Importance of Gratitude**	**15-minute practice-** Mountain meditation. Review last week and home exercises **Activity** - play video "Underlying Calm" **Discussion -** The mental state of "appreciative joy" is discussed and practiced. Observe without judgment and focus on the good. impact on social relationships. **Activity** - Write or draw in your journal what make you feel good, what you are thankful for. **5-minute practice** - open awareness. **H.W. -** practice for 10 minutes three times this week. **Online session:** 10 minute practice, brief review of this week's topic and end with one minute of meditation.
Week 9	**15-minute practice-** Mountain meditation. **Review last week and home practice.**

Naming Thoughts and Emotions	**Activity** -play video "You are not your thoughts" **Discussion-** observing and naming thoughts and emotions with compassion and curiosity. noticing pleasant, unpleasant, and neutral sensations. Knowing the mind and the importance of being able to choose what to attend to. **10 minutes practice** - open awareness, practice outside, bring awareness to sounds and body sensations **Homework -** practice for 10 minutes three times this week. **Online session:** 10 minute practice, brief review of this week's topic and end with one minute of meditation.
Week 10 Compassion and Metta Meditation	**15-minute practice-** Metta meditation. **Review** last week and home exercises. **Activity** -video -Why Focus on the Happiness of Others? **Explain** how mindfulness cultivates compassion. **Discussion** -what is compassion? why be compassionate? mutual struggles. Bringing mindfulness into communication and relationships. **Mindfulness** - 15 minutes of love and kindness practice. **Homework:** practice for 10 minutes three times this week. **Online session:** 10 minute practice, brief review of this week's topic and end with one minute of meditation.
Week 11 Implementing Mindfulness in Everyday Life	**15 minute practice-** walking/stretching meditation **Review** last week and home exercises**.** **Explain** - the concept of transfer. practicing formal mindfulness will help transfer this ability to other contexts. **Discussion -** regular practice can increase self-control and relief emotional stress. **5-minute practice** - focus on body sensations. **Homework** practice for 10 minutes three times this week. H**ome session** - online 30-minute session including a 15-minute mutual practice focus on the breath. **Online session:** 10 minute practice, brief review of this week's topic and end with one minute of meditation.
Week 12	**15 minute practice-** Focus on the breath R**eview** - What is mindfulness? What topics did we discuss?

Review and Summary	**Discussion** -how was the course? What have you learned? What will you take with you? How to maintain a practice routine and a mindful state. **Group reflection**. M**indfulness practice** - 10 minutes - open awareness.

APPENDIX B.

In-Person Session Example

1. Opening - participants gather in the room. The instructor greets everyone and immediately begins a 10 minute guided Mindfulness meditation practice: Focus on the Breath.
2. Discussion - The instructor invites the participants to share their experiences during the practice and passes a symbolic speaking stick. Participants are not obligated to share.
3. Discussion 2 - The instructor leads with questions about last week's topic and encourages participants to share their experiences during the home practice exercises.
4. Topic presentation "Being Present." The instructor brings a big glass bowl of water to a table in the center of the room. He gives the participants various small objects such as paper scraps, fabrics, marbles, paint, colorful strings, and more. The instructor explains that the bowl of water represents the mind. When we are present, our mind is clear, and we can see through the water, think clearly, and focus on what we are currently doing. However, our minds can quickly become unclear. This happens when we start to think about things that are not related to what is currently happening in the present moment. It can be thoughts about the future or past, positive thoughts, or concerning thoughts. The instructor gives an example: he takes a marble and says this marble represents my thought about what I will have for dinner today and puts the marble in the water. He picks up

another object and says this fabric represents my thoughts about an argument I had with my friend yesterday and places the fabric in the water bowl. He takes the third object, saying it represents his back pain, and puts it in the bowl. He then invites the participants to share a thought, emotion, or sensation they can get in their minds and take an object representing that and putting it in the water bowl. When all the participants are done sharing, the instructor asks what has happened to the clarity of the water? He explains that when we have all these thoughts, our mind becomes unclear. This state prevents us from being present and thinking clearly. A cluttered mind makes it harder to control our behavior and react as we would like. Our mind is used to being in this clutter. In fact, people have more than 6000 thoughts per day. But this state but through Mindfulness practice, we can train our mind to stay clear, which can help us think clearly and behave according to our values. It is usual for our mind to begin thinking about the past or future when we are still. Some call it the monkey mind. Imagine a monkey inside our head that keeps jumping from thought to thought, making clutter in our mind, especially when you are practicing Mindfulness and being still. Our goal in this program is to train this monkey to stay still. and keep our minds clear

5. Activity: Instructor plays video: Training the Monkey Mind
6. Instructor - We train the monkey to stop creating clutter by practicing Mindfulness. We repeatedly shift our attention from any thought or sensation to the object of focus (Breath, sound ext.). During a Mindfulness practice, this shift can happen dozens and even hundreds of times. Our goal is to practice this shift

from the thought to the object of focus.

7. Discussion: what does it mean to be present? How does our mind become cluttered?
8. Summary - The instructor summarizes the session
9. Journaling - The instructor invites the participants to write what they have taken from the session in their journals.
10. Home assignment: choose one activity such as brushing your teeth, taking a shower, or walking your dog and try to do it with a clear mind. Focus on the actual activity you are doing. For example, focusing on the water temp in the shower or the sensation of the toothbrush on your teeth, or your hand movement when brushing your teeth. When you notice that the monkey mind is jumping to other thoughts, gently bring him back to focus on your activity. Set a reminder on your phone to help you remember to practice this routine activity.
11. Guided Mindfulness practice 5–10 minutes. End of session.

APPENDIX C.

Participants Survey

How do you feel about the following statement? Please fill an X in the box that best describes your opinion.

	Statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1	The online sessions from home were beneficial for me.					
2	The content was delivered at an appropriate pace for me					
3	The instructor explained new concepts in a way I could understand.					
4	The topics discussed in the group were relevant for me					
5	The activities were helpful for my learning					
6	I learned to practice mindfulness during the program					
7	I think practicing mindfulness could help my wellbeing					
8	The videos help me understand the topic of the session.					
9	I benefited from the group discussions.					
10	I plan to continue to practice mindfulness.					

APPENDIX D.

Daily Behavior Checklist

In this sheet you are requested to report any aggressive behavior including anger outbursts, shouting, cursing, verbal or physical violence, loss of control, inappropriate sexual behavior. The titles in red are essential for the report, it is recommended to briefly describe the incident including the trigger and the behavior. No report on a certain date means no problematic behavior occurred.

Date	Time of Day	Intensity (Circle your answer)	What Happened?
		1 2 3 4 5 6 7 8 9 10	
		1 2 3 4 5 6 7 8 9 10	
		1 2 3 4 5 6 7 8 9 10	
		1 2 3 4 5 6 7 8 9 10	
		1 2 3 4 5 6 7 8 9 10	
		1 2 3 4 5 6 7 8 9 10	
		1 2 3 4 5 6 7 8 9 10	

APPENDIX E.

Focus Group Questions

- Did you find the CALM beneficial for you?
- What was your most favorable part of the program? and why? (Group discussion, group activities, home practice, videos, guidance)
- What was the least favorable part of the program? and why?
- How was your experience from the home-based sessions? (Technical, setting, schedule etc.)
- What would you change in the program? (Duration of each session, topics and content, activities. instruction, schedule, location)
- What was the most challenging in your participation in the program?
- Would you recommend this program? If you answered no, why not?

APPENDIX F.

Fact Sheet

BOSTON UNIVERSITY

Cultivating Awareness by Living Mindfully- CALM

Group intervention for emotional regulation of adults with TBI

Adi Segal, OTD candidate

What is the Problem?

- Traumatic Brain Injury (TBI) contributes to global mortality and disability more than any other traumatic injury and therefore poses a significant public health concern.
- Common emotional changes after TBI include anger outbursts, physical aggression, low self-awareness, impulsivity, rumination, and more (Hart et al., 2020; O'Keeffe et al., 2020)
- The effects of a TBI contribute to the individual's inability to regulate emotions and thus maintain and form social relationships and participate in life events and activities (Manolov et al., 2019; Toglia & Golisz, 2017)
- Extensive evidence shows that emotional regulation is not effectively addressed by common traditional interventions (Gómez-de-Regil et al., 2019; Lee, 2019; Oddo et al., 2016)

Proposed Solution - CALM

- The CALM program aims to make Mindfulness practice (referenced below) and its many health benefits accessible and possible for individuals post-TBI.
- The program is based on a carefully constructed combination of occupational therapy, learning, and Mindfulness theories and practice.
- The CALM program consists of 12 weekly lessons. Each week includes an in-person group session, followed by an online session delivered in the persons' home.

Guiding Theories

- Mindfulness - This approach promotes mindfulness practice leading to increased awareness of automatic behaviors and reactions, and how they can cause emotional distress, which contributes to acceptance and emotional control (Kabat-Zin, 1982)
- The MultiContext approach - Occupational therapy framework that focuses on practicing learned skills in different contexts and settings to support their transfer and generalization (Toglia et al., 2010)
- Brain-Based Learning - The program follows principles from the latest scientific research for optimizing learning in adults who have sustained a TBI (Jensen, 2008).

Expected Outcomes

- Improvement in the ability to regulate emotions.
- Increase in self-awareness.
- Increase in Mindfulness trait.

All of these contribute to increased participation and engagement in all activities of daily living and interactions.

Implications for Occupational Therapy Practice

- "Occupation is the activist element of human existence whether occupations are contemplative, reflective, meditative or action based" (Durocher, Rappolt, & Gibson, 2014).
- Occupational therapy (OT) is an integral part of the optimal rehabilitation process of people who sustained a TBI.
- The CALM intervention program, which is based on occupational therapy frameworks and principles, supports the provision of OT services for the rehabilitation of this population.
- By integrating the use of mindfulness techniques into evidence-based occupational theories, individuals with TBI can improve their ability to regulate their emotions, in turn improving their ability to actively participate in meaningful occupations and relationships.
- CALM provides occupational therapists with tools to enhance emotional regulation and wellbeing for an optimal rehabilitation process for people with TBI.

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APPENDIX G.

Executive Summary

Cultivating Awareness by Living Mindfully - CALM

Introduction

Traumatic brain injury (TBI), also known as the "silent epidemic," contributes to global mortality and disability more than any other traumatic injury, and thus poses a major public health concern with loss of economic productivity and increased healthcare utilization. TBI is defined as a disruption to the brain's normal function, caused by a bump, blow, or jolt to the head (DCD, 2017). The precise prevalence and incidence of TBI remains unknown (Bell et al., 2017). A large systematic review (Dewan et al., 2018) estimates that every year approximately Sixty-nine million individuals sustain a TBI around the world annually. National investigations suggest that approximately 5.3 million people live with TBI-related disabilities in the U.S. (Selassie et al., 2008; Zaloshnja et al., 2008), and that 12% of the adult U.S. population have a history of TBI (Frost et al., 2013).

Interventions for individuals with TBI require many professionals, including medical staff (MD and nurses), occupational therapy, social workers, vocational rehabilitation, physical therapy, and more. Only a few studies examined the economic burden of TBI on families, employment, and society as a whole. The latest and most comprehensive study, conducted in 2010, suggests that the total cost related to TBIs in the United States alone is $76.5 billion, including medical expenses, loss of productivity, and more (CDC, 2019; Humphreys et al., 2013). Beyond the substantial financial impact of TBIs on the global economy, the emotional and social effects invoked by TBIs weigh a

significant burden on society.

Individuals who sustained a TBI report profound changes in their cognitive, physical, and emotional functions. Common emotional changes after TBI include anger outbursts, physical aggression, low self-awareness, impulsivity, rumination, depression, and anxiety (Geraldina et al., 2003; Hart et al., 2020; O'Keeffe et al., 2020; Toglia & Golisz, 2017). The effects of a TBI contribute to the individual's inability to control emotions and thus maintain and form social relationships and participate in life events and activities (Manolov et al., 2019; Mateer & Sira, 2006; Toglia & Golisz, 2017). The effect of a TBI goes beyond the individual's struggles, naturally extending to the caregiver and family. Following the injury, family members cope with "losing" the person they knew and learning to accept the changed personality of their loved one (Blais & Boisvert, 2005; Pugh et al., 2018; Tam et al., 2015). Coping with extreme behaviors can negatively impact families and caregivers' quality of life (Anderson et al., 2013; Pugh et al., 2018). This wide range of short and long-term outcomes influences the person, their close environment, and the community. The urgent need to enhance emotional regulation to improve the health and well-being of people with TBI and their families is the main goal of this doctoral project.

Current Therapy Approaches

The optimal rehabilitation process for individuals who sustained a TBI is holistic and addresses the various aspects of life. The process requires the services of health professionals from different disciplines, making the rehabilitation process more costly, and often has a limited impact on desired outcomes (Lee, 2019; Sveen et al., 2020).

Current traditional approaches and methods for the rehabilitation of people with TBI include pharmacological treatment, cognitive rehabilitation, psychotherapy, behavioral interventions, Cognitive Behavioral Therapy (CBT) and more. While these therapy approaches have been beneficial for some of the mentioned challenges, extensive evidence shows that emotional regulation is not effectively addressed (K. D. Cicerone et al., 2011; Gómez-de-Regil et al., 2019; Lee, 2019; Oddo et al., 2016). These therapy approaches often focus on identifying and correcting negative thoughts, leading the person to change their behavior solely in the context where the approach was practiced. The skills may not effectively transfer outside of the clinician's office thus the clients continue to exhibit problematic behaviors in other settings. Moreover, some studies suggest that the process of examining the origins of thoughts, emotions, and behaviors which is common in traditional cognitive rehabilitation, psychotherapy, and CBT can also be inaccurate and misleading (Lee, 2019; Ryle, 2012; Sveen et al., 2020; Wheelahan, 2009) .

In contrast to the current traditional therapy addressing emotional regulation of individuals with TBI, a Mindfulness-based approach focuses on observing and accepting thoughts, sensations, feelings, and surroundings with an open and curious mindset rather than reacting automatically (Alsubaie et al., 2017; Azulay & Mott, 2016). Interventions based on Mindfulness are becoming increasingly prevalent, with growing evidence of the benefits of these interventions in the brain injury population (Marchand et al., 2021; Moulton-Perkins et al., 2020). Nevertheless, the standard Mindfulness interventions available for adults with TBI do not accommodate for the specific challenges these

individuals cope with, making it inaccessible for them to participate in this type of interventions. Therefore, there is a need for a Mindfulness-based intervention program that is specifically developed for this population, based on principles of cognitive rehabilitation, and learning approaches.

Program Overview

Cultivating Awareness by Living Mindfully: CALM; it is a Mindfulness-based group intervention for adults who sustained a TBI. The program goals are to increase self-awareness and improve emotional regulation by learning to practice mindfulness techniques and implementing them in everyday activities and interactions.

The theoretical foundations are based on complementing knowledge bases: The content and techniques are based on Buddhism and Mindfulness. The delivery approach and adaptations for cognitive and physical impairments (such as memory, attention, and regulation difficulties) are based on evidence of Mindfulness-based interventions for TBI, and occupational therapy's the MultiContext approach (Toglia, 1991), and brain-based learning.

Main Theoretical Frameworks

The proposed program incorporates principles from the latest evidence-based therapy approaches and principles designed specifically for individuals who sustained a TBI. Research evidence on methods to enhance learning for the TBI population informed the structure and teaching approaches of each session. The main frameworks implemented in the program include:

Mindfulness-Based Therapy

Mindfulness techniques originate from Buddhist meditation practices and adapted for clinical settings by Jon Kabat-Zinn (1982), that defines Mindfulness as paying attention in a particular way: on purpose, in the present moment, and non-judgmentally. Mindfulness-based interventions aim to achieve a mental state of focus on the present moment with non-judgmental awareness. According to this approach, the person can improve his/her emotional well-being by increasing awareness of how automatic behaviors and reactions can cause emotional distress. Individuals are encouraged to acknowledge and accept their thoughts, sensations, feelings, and surroundings with an open and curious mindset rather than reacting automatically. By focusing on the present, rather than ruminating on the past or worrying about the future, participants can cope with stressors that often lead to anxiety or emotional regulation difficulties (Kabat-Zinn, 1982; Robinson et al., 2019).

The MultiContext Approach

The MultiContext approach (Toglia et al., 2010; Toglia, 1991) is a cognitive rehabilitation therapy approach. The key goals are the transfer and generalization of learning to different contexts as the therapy program's main goals. These goals are achieved through the practice of metacognitive strategies in different contexts to increase awareness and generalization of those strategies. Tasks and environments are increasingly changed, but the strategy and techniques remain the same. Participants in the CALM intervention program will engage in online sessions from home and receive a variety of practice activities that aim to increase the transfer and generalization of

mindfulness techniques.

Brain-Based Learning

Establishing the learner's profile of individuals who sustained a TBI is vital in the success of rehabilitation programs. Brain-Based Learning (BBL) refers to education methods based on the latest scientific research on how the brain learns best (Jensen, 2008). For example, people with TBI require more learning trials than people with no TBI to learn the same amount of information (DeLuca et al., 2000; Zipse, 2020), so repeating important information and practices can improve learning. Furthermore, it has been proven that repetition will facilitate memory and recall more effectively in a spacing format (Haslam, 2017; Hillary et al., 2003). When controlling the amount of information acquired during repeated learning trials and spacing between repetitions, individuals who sustained a TBI improved their memory recall and recognition of learned information (Haslam, 2017). The program follows these principles and more have been shown to significantly improve the learning process of adults with a TBI.

The CALM intervention program was developed based on these evidence-based approaches and designed to support optimal learning and implementation of mindfulness techniques into activities and interactions. These practices support emotional regulation and increased self-awareness. Both are associated with a better quality of life and well-being.

Program Structure

The CALM program lasts 12 weeks. Each week includes an in-person group session, followed by an online group session delivered in the persons' home. Each session begins with a 5–15-minute Mindfulness practice, focused on observing thoughts, emotions, and sensations, and continues with a review of last week's session and home exercises. Following that, the instructor presents the session's topic, conducts a group activity designed to explain abstract concepts associated with Mindfulness and generates a discussion. Furthermore, each session includes watching an information video about the topic of the session, and participants are asked to freely document in a personal journal what they have learned in this meeting. Each session is completed with another 5–15-minute Mindfulness practice, and participants receive a home activity for Mindfulness practice.

Evaluation of CALM Effectiveness

The evaluation plan for CALM aims to measure changes in self-awareness and emotional regulation. The research study process includes formative and summative components. The formative evaluation component explores whether the program is operating as planned and examines if the program's delivery, components, and content are feasible, beneficial, and assists in optimizing the program. Information will be gathered following program completion. The summative evaluation component is aimed at exploring and establishing connections between the CALM intervention program and the outcomes by analyzing quantitative numerical data to be collected prior to and following program participation. This section will include standardized measures to

evaluate changes in emotional regulation and self-awareness. This single-subject design study will take place at a rehabilitation center for adults with a TBI such as the Veterans Affairs (VA) facility or a community center that provides services to individuals with TBI. Participants will include four to six adults over the age of 18 who sustained a TBI, are at least 1-year post-injury, and experience challenges in emotional regulation reported by the participants and family members or caregiver. The participants should live in the community with a family member or caregiver. The study will examine the frequency of inappropriate or aggressive behaviors, and changes in emotional regulation, based on standardized measures (The Patient Competency Rating Scale, The Overt Behavior Scale, The Difficulties in Emotion Regulation Scale, The Five Facet Mindfulness Questionnaire), and reports from participants and their family members. Also assessed is the participants' use of Mindfulness in their daily life and their overall satisfaction with the program. This study's results will establish the benefits of CALM and its contributions to participants improved emotional regulation and increased self-awareness.

Funding The CALM Program

The CALM program was developed to be a low-cost program that can be implemented in diverse settings. The cost of funding CALM requires the amount of approximately $1,500 for a 3-month group program, which includes 6-8 participants. Funding for the program can be done via insurance coverage, paid out of pocket, invested by a hosting rehabilitation center or community facility, or by a grant for health services targeting the TBI population, such as The Administration of Community Living (ACL), which provides funding for rehabilitation programs for adults who sustained a TBI.

Conclusion

The CALM program makes mindfulness and its many health benefits accessible and possible for individuals post TBI. The program is based on a carefully constructed combination of rehabilitation, learning, and Mindfulness theories and practice. CALM focuses on teaching adults who sustained a TBI to practice Mindfulness techniques and implement them to everyday tasks and social interactions. The anticipated outcomes are an improvement in emotional regulation and increased self-awareness that contribute to a better quality of life.

The low cost of the program makes it feasible for implementation in a variety of health or community settings. It is the authors hope that the results of the effectiveness study are widely disseminated in professional venues and to potential clients and inform future services and policy evaluation. Healthcare professionals, administrator's and organization's support in CALM will establish this evidence-based intervention program as beneficial for people with TBI.

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